ConsCIOUS-3:

Noradrenergic Suppression to Reduce Connected Consciousness After Intubation- A Randomised, Placebo-Controlled Trial

Protocol Number:	X210410
Principal Investigator:	Professor Robert Sanders Robert.Sanders@sydney.edu.au
Protocol Authors:	Professor Robert Sanders Dr. Daniel Carayannis Dr. James Booth Kaitlin Kramer
Protocol Version:	Version 1.2
Protocol Date:	15/11/2021

Principal Investigator:

Professor Robert Sanders

Signature:_____ Date:_____

Ethics Statement:

The study will be conducted in accordance with the *National Statement on Ethical Conduct in Human Research* (2007), the *CPMP/ICH Note for Guidance on Good Clinical Practice* and consistent with the principles that have their origin in the Declaration of Helsinki. Compliance with these standards provides assurance that the rights, safety and well-being of trial participants are respected.

Contents

Summary

Study title:	ConsCIOUS-3: Noradrenergic Suppression to Reduce Connected Consciousness after Intubation- A randomised, placebo-controlled trial
Protocol version:	Version 1.2 , Dated 15 November 2021
Objectives	
Primary objective:	Pilot study of whether dexmedetomidine may reduce rises in the Bispectral Index
Secondary objectives:	Pilot study of whether dexmedetomidine may: 1) Reduce isolated forearm technique responsiveness after intubation 2) Confirm the safety of adjunct dexmedetomidine for intubation 3) Pilot whether dexmedetomidine is useful in females to reduce BIS arousal 4) Instance and severity of post-operative delirium
Study design:	Randomized Controlled Trial, sex-based stratified randomisation
Planned sample size:	52 subjects
Selection criteria:	Healthy (ASA 1, 2 or 3) subjects undergoing intubation for general anaesthesia
Study procedure:	Single Site, randomized control trial, trial drug (dexmedetomidine) or placebo given during general anaesthetic induction.
Statistical considerations:	Sample size calculation Yes Analysis plan Yes
Duration of Study	1 year

1. BACKGROUND AND INTRODUCTION

1.1. DISEASE/PROPOSED INTERVENTION BACKGROUND

Anaesthesia is proposed to be a state of unawareness, and explicit memory of intraoperative events is rare (0.1-0.2%)[1-4]. However, intraoperative awareness, without explicit recall, may occur in at least 5% of subjects[5,6]. While a 5% intraoperative awareness rate is several orders of magnitude higher than the incidence of explicit memory under anaesthesia, a subgroup analysis of first study suggested the rates may be up to 12% in patients under 40 years old[5]. Hence, we conducted ConsCIOUS2, focussed on young adults (18-40 years old), who are typically considered high risk for awareness, and identified that 11% of young adults showed evidence of intraoperative awareness. Importantly, females were more likely to respond than males ($OR_{adjusted}$ = 2.7, 95% CI [1.1, 7.4], p=0.024), behoving us to identify ways in which to address this issue.

Our recent survey of the public identified that 60% of participants felt it was unacceptable to be aware of intraoperative events even if they could not recall them afterwards[7]. Further, implicit memory and intraoperative awareness have been associated with reduced postoperative satisfaction, dysphoria and post-traumatic stress disorder[3,5,8].

In order to assess intraoperative awareness in a way that is not dependent on memory, we employed the isolated forearm technique[9]. A sphygmomanometer cuff is inflated on the forearm to isolate the hand from the circulation, preventing it being paralysed during neuromuscular blockade. Subjects are then asked to squeeze a researcher's hand to signify a volitional response to command, which in humans, is the gold-standard definition of consciousness.

1.2. RATIONALE FOR PERFORMING THE STUDY

Given the known role of noradrenaline in (1) the fight or flight response, (2) awareness to external stimuli, including through salience-driven attention mediated by the ventral attention network, and (3) the relative lack of suppression of the locus coeruleus by propofol and volatile anaesthetic agents, we have hypothesized that additional noradrenergic suppression may be required to reduce the incidence of intraoperative awareness[6]. Furthermore, there are some data suggesting that this may particularly advantage females[10]. Dose of anaesthetics required to induce loss of consciousness varies by stage of menstrual cycle and so, as a secondary endpoint in females, we will assess how menstrual cycle affects the endpoints in this study[25]. Herein, we will conduct a pilot randomized controlled trial to provide preliminary data to support a larger study to refine induction techniques in anaesthesia for young people. This pilot study is powered to focus on EEG arousal and in the future we plan to power investigations for intraoperative awareness.

<u>Dexmedetomidine, Propofol and Induction of anaesthesia</u>

Propofol is the most utilised induction agent in anaesthesia worldwide. However, it is often coupled with an analgesic as it does not have any analgesic properties in and of itself. Controlling the intense stimulus of intubation is important as it can cause a hypertensive crisis and awareness if not managed appropriately. The alpha2 adrenoceptor agonist dexmedetomidine has been compared against propofol for the induction of anaesthesia and interestingly dexmedetomidine was better at maintaining haemodynamic stability than propofol[11]. Dexmedetomidine usually however cannot achieve complete anaesthesia on its own, however a combination with propofol could be a clinically useful combination.In particular dexmedetomidine has shown to be safe and efficacious as a premedicant, particularly in children, where its sedating and anxiolytic properties are particularly helpful.

Dexmedetomidine has been tested against endpoints designed to observe this. In this crossover design study, one group of patients were commenced on a dexmedetomidine infusion to achieve a steady plasma concentration of 0.66ng/ml. After this was achieved a propofol infusion was gradually increased and endpoints tested against a saline control group. These endpoints included concentration of propofol required to achieve loss of ability to hold a syringe, loss of eyelash reflex, and loss of motor control to electrical stimulation. The amount of propofol required to achieve these endpoints was shown to be just over half the requirement in the test group vs the control group, demonstrating an advantageous pharmacodynamic interaction between the two drugs[12].

Our main interest of enquiry is the usefulness of dexmedetomidine during intubation and there have been a number of studies which demonstrate the effects of this. The usual loading dose of dexmedetomidine used to study this effect is 1microg/kg as a bolus, along with propofol to achieve loss of consciousness. All of these studies show a significant reduction in haemodynamic response to intubation when dexmedetomidine is utilised during intubation as compared to saline placebo[13,14,15,16,17,18]. These studies measured changes in blood pressure and heart rate, insinuating that dexmedetomidine attenuates the haemodynamic response via attenuation of catecholamine release, however this has not specifically been measured directly via blood sampling. In a direct comparison with the beta blocker labetalol, dexmedetomidine was also considered superior in achieving haemodynamic stability with fewer adverse side effects[14].

Whilst most studies utilise a 1mcg/kg loading dose of dexmedetomidine, it does appear that even a 0.5mcg/kg loading dose is significantly effective, whilst reducing the unwanted side effects of dexmedetomidine such as bradycardia and hypotension. A randomised double blind placebo controlled study compared the effects of a 0.5microg/kg loading dose and a 1microg/kg loading dose of dexmedetomidine, and compared both to a saline control. Both loading doses showed equal effectiveness in reducing propofol dose required for induction, and blunting the haemodynamic response to laryngoscopy and intubation. The lower dose was associated with less hypotension and bradycardia[19].

In addition, a 2015 study utilised 0.5microg/kg loading of dexmedetomidine and demonstrated that the mean total dose of propofol required for induction was almost half of that in the control group. It also showed an approximate 33% reduction in systolic blood pressure rise, an approximate 40% reduction in diastolic blood pressure rise, and approximately 35% reduction in mean blood pressure rise[20].

It should be noted that the bispectral index (BIS) depth of anaesthesia monitor can monitor loss of consciousness when dexmedetomidine is utilised in addition to propofol as compared to propofol alone or in combination with an opioid[21,22].

It is worth stressing that dexmedetomidine has shown to be safe and efficacious as a premedicant, particularly in children, where its sedating and anxiolytic properties are particularly helpful[24] and hence in this context dexmedetomidine can be considered in line with standard of care.

2. HYPOTHESIS

We hypothesize that dexmedetomidine will reduce the rise in "brain activity" detected by the Bispectral Index (BIS) monitor following intubation.

3. STUDY OBJECTIVES

3.1. PRIMARY OBJECTIVES

1. To determine if adjunct dexmedetomidine may reduce increases in the BIS following intubation

3.2. SECONDARY OBJECTIVES

1. Pilot study of whether dexmedetomidine may reduce isolated forearm technique responsiveness after intubation
2. To confirm the safety of adjunct dexmedetomidine for intubation.
3. To pilot whether dexmedetomidine is particularly useful in females in reducing BIS arousal
4. To test whether adjunct dexmedetomidine reduces the incidence of intraoperative awareness after intubation assessed by the isolated forearm technique
5. To investigate stage of menstrual cycle, anaesthetic dosing and response to intubation

4. STUDY DESIGN

4.1. DESIGN

The study is a randomised (saline) controlled trial of 52 participants with sex-stratified randomization.

4.2. EXPECTED PARTICIPANT NUMBERS
N=52

4.3. DURATION OF THE STUDY
1 Year of Recruitment at RPAH.

4.4. ENDPOINTS

PRIMARY ENDPOINTS

Rise in BIS values from pre-intubation to post-intubation

SECONDARY ENDPOINTS

1. Responsiveness on the IFT post-intubation between groups
2. Changes in perioperative blood pressure and heart rate
3. Sex-based differences in BIS, IFT and haemodynamic responsiveness to dexmedetomidine
4. The frontal EEG characteristics of responsiveness or not on the IFT
5. The association of stage of menstrual cycle with dose of anaesthetics required for loss of consciousness or BIS rise following intubation or responsiveness on IFT.
6. Incidence and severity of postoperative nausea and vomiting
7. Visual analogue score for pain
8. Instance and severity of post-operative delirium

8.5. CENTRES

Royal Prince Alfred Hospital

5. STUDY PARTICIPANTS

5.1. INCLUSION CRITERIA

Adults requiring intubation for general anaesthesia

Sex: Females and Males

Age range: 18-40 years old

Willingness to Provide informed consent and participate and comply with study requirements

Healthy (ASA status 1, 2 or 3)

Support of treating surgical team for participant's involvement (this will be acquired prior to the day of surgery)

5.2. EXCLUSION CRITERIA

Women lactating, or pregnant.

Participants with a history of allergy to dexmedetomidine or history of heart block.

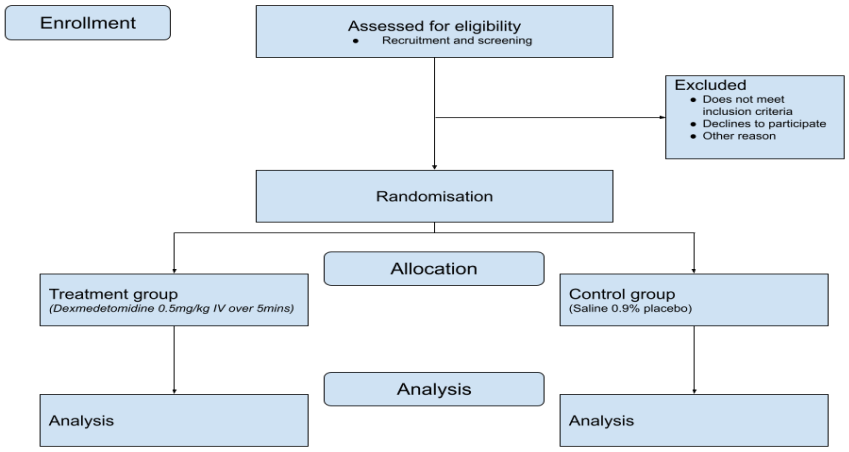
Participants who may have received an investigational new drug within the last 7 days

Participants with a history of a psychological illness or other conditions which may interfere with their ability to understand the study requirements.

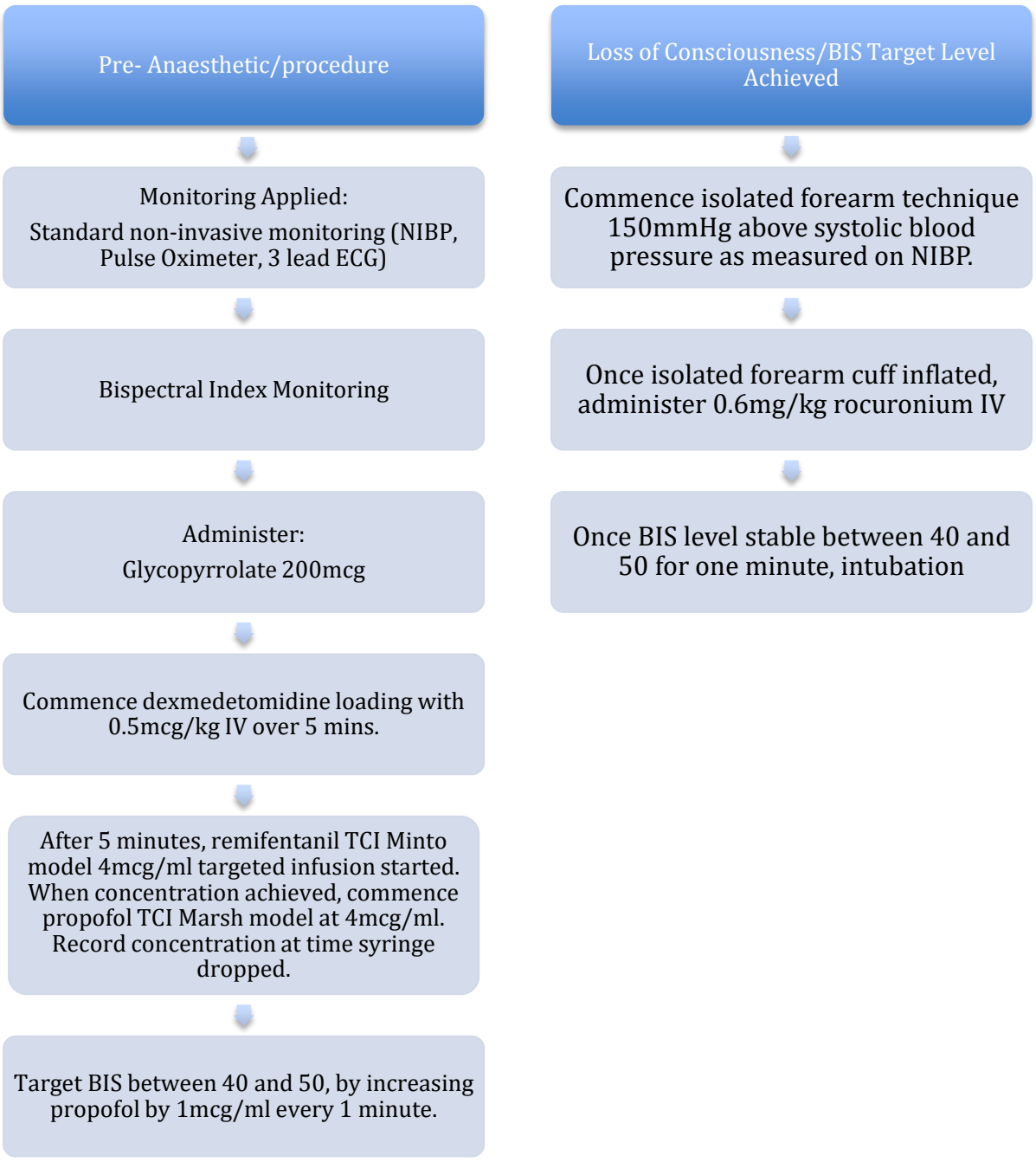
Participants with cognitive impairment that is likely to interfere with the evaluation of the participant's safety and of the study outcome.

6. STUDY PROCEDURES

6.1. STUDY FLOW CHART



See Below for more detailed Flow Chart following Enrolment/Randomisation


Pre- Anaesthetic/procedure
Monitoring Applied:
Standard non-invasive monitoring (NIBP, Pulse Oximeter, 3 lead ECG)
Bispectral Index Monitoring
Administer:
Glycopyrrolate 200mcg
Commence dexmedetomidine loading with 0.5mcg/kg IV over 5 mins.
After 5 minutes, remifentanil TCI Minto model 4mcg/ml targeted infusion started. When concentration achieved, commence propofol TCI Marsh model at 4mcg/ml. Record concentration at time syringe dropped.
Target BIS between 40 and 50, by increasing propofol by 1mcg/ml every 1 minute.
Loss of Consciousness/BIS Target Level Achieved
Commence isolated forearm technique 150mmHg above systolic blood pressure as measured on NIBP.
Once isolated forearm cuff inflated, administer 0.6mg/kg rocuronium IV
Once BIS level stable between 40 and 50 for one minute, intubation

Measurements:

- NIBP minutely
- Heart rate minutely
- BIS value
  - Pre-dexmedetomidine baseline
  - Post dexmedetomidine at 1, 3 and 5 mins (Pre-induction)
  - Post induction every 2 minutes.
  - Post intubation at 1, 2, and 5 mins
- Dose of propofol for loss of consciousness (syringe drop)
- Positive or negative physical response (defined as IFT responsiveness within 1 min of intubation)
  - Confirmed with blinded video assessments
- 24 hours post operative, pt interviewed and asked if any awareness of events during induction of anaesthesia.
- Frontal EEG differences between dexmedetomidine and placebo

6.2. INVESTIGATION PLAN

Methodology

Interventions	Enrolment Visit	Visit 1 Intraoperative Care	Visit 2 (PACU 15 min and 60 min)	Visit 3 Postoperative visit 24 hours	Visit 4 Postoperative visit 7 days
Participant Consent	X				
Inclusion/ Exclusion Criteria	X				
Pre-Operative Questionnaire (Females)	X				
Randomisation & drug treatment		X			
BIS/EEG and IFT data		X			
Anxiety/Pain/ PONV Score			X		
Delirium Assessments*			X		
Brice and satisfaction questionnaire				X	X
Adverse Event & Serious Adverse Event Assessment		X		X	

All intra-operative procedures including the administration of dexmedetomidine follow standard practice within general anaesthesia.

*As per the Case Record File (appendix 1) the post-operative delirium assessments will be conducted in recovery at 15 minutes post-operation and 60 minutes post-operation. The assessments will include the Richmond Agitation and Sedation Scale (RASS), Confusion Assessment Method ICU (CAM-ICU) and Nursing Delerium Screening Scale (NuDESC).

6.3. STUDY PROCEDURE RISKS

Dexmedetomidine is an approved sedative and can induce hypotension, bradycardia and complete heart block. This risk is increased when used in combination with other sedating

agents. However, the risk of these events is most often seen in the elderly and patients with comorbidities (e.g. diabetes, chronic hypertension, severe cardiac disease). The risk of bradycardia will be offset by the addition of glycopyrrolate/atropine as a premedication and the population to be assessed will be young patients (18-40)). The expected haemodynamic effects of combining dexmedetomidine and propofol will also be offset by a likely overall dose reduction of propofol to achieve the desired BIS. On balance the approach of combining dexmedetomidine and propofol should not increase risk, consistent with prior publications[19,20].

6.4. PARTICIPANT RECRUITMENT AND SCREENING

Participants will be screened using the surgical lists and their date of birth to ensure they meet basic eligibility criteria. Their medical history and ASA status will also briefly reviewed by a member of the research team (within the department of anaesthetics) or by anaesthetic doctor to ensure they are ASA 1-3 and have no serious medical issues.

The participant will be approached in the pre-admission clinic or over the telephone prior to the day of surgery, during this call they will be provided with information on the trial in both verbal and written form. They will be given sufficient time to think discuss their involvement with their family and ask questions.

During the screening and recruitment process the treating surgical team will be contacted to ensure their support for the participant to be involved in the research project.

6.5. PARTICIPANT ENROLMENT

Potential participants will be enrolled into the study after they have been given sufficient time to read the patient information sheet and process the information/discuss with their family. Study participants will receive a study enrolment number and this will be documented in the participant's medical record and on all study documents.

During patient enrolment and consent female participants will be asked to complete a questionnaire on contraception and menstruation (see appendix).

6.6. INFORMATION AND CONSENT

Informed consent will be obtained from eligible patients prior to their procedure. Participants will be assessed for ability to given informed consent, their literacy/language abilities and risk of unequal power dynamics in patient/doctor relationships. A Patient Information Consent Form with their signature and signature of the study doctor or research coordinator will be copied and filed in their medical records and study file. Additionally, the patient will receive a copy of this document.

Where feasible electronic consent will be obtained using RedCAP.

6.7. RANDOMISATION PROCEDURE

The participant will be randomized by computer program (RedCap) prior to their surgery. At this visit the participant will be randomised to saline or dexmedetomidine and receive a Randomisation Number.

The member of the research team randomising the participant will provide the randomisation details to the treating anaesthetist who will administer the intervention or placebo, they will not be blinded to the intervention. Members of the research team will conduct post-operative assessments and follow up will be blinded to the treatment arm.

6.8. END OF STUDY TREATMENT/WITHDRAWAL PROCEDURE

The study will end at 7 days postoperatively.

6.9. PATIENT WITHDRAWAL

A patient may withdraw their consent at any time with no change to their surgical and post-surgical standard care.

7. OUTCOMES

7.1. The outcomes of this trial will be documented in the CRF and include:

1. Change in BIS value from pre-intubation to post-intubation
2. Responsiveness on the IFT post-intubation between groups
3. Changes in perioperative blood pressure and heart rate
4. The frontal EEG characteristics of responsiveness or not on the IFT (collected from the BIS monitor).

8. STATISTICAL CONSIDERATIONS

8.1. SAMPLE SIZE OR POWER CALCULATION

Power calculation:

Based on[23], 50 subjects provides 90% power ($p<0.05$) to show a difference of 10 points in the BIS (SD = 11)[23]. We include 2 extra patients for loss to follow up. Total sample size is 52 participants.

8.2. PROVIDE A DETAILED ANALYSIS PLAN

1. Rise in BIS value from pre-intubation to post-intubation analyzed by t-test (parametric) or Mann-Whitney (non-parametric)
2. Responsiveness on the IFT post-intubation between groups (Fischer's Exact test)
3. Changes in perioperative blood pressure and heart rate analyzed by t-test (parametric) or Mann-Whitney (non-parametric)
4. The frontal EEG characteristics of responsiveness or not on the IFT (collected from the BIS monitor). We will calculate the power spectrum and then subdivide by power bands using matlab pwelch function. We will average the power for the 10s prior to intubation and test whether there are differences in power, analyzed by t-test (parametric) or Mann-Whitney (non-parametric). We will repeat this process for the 10s after intubation. Further analyses of the EEG may be then undertaken to identify differences in IFT responders or not.

9. DATA COLLECTION

9.1. PARTICIPANT REGISTRATION

Participants will be registered for the trial at the time of consent and will be provided with a study ID. On the day of surgery, the participant will be randomized by computer to dexmedetomidine or placebo.

9.2. FORMS AND PROCEDURE FOR COLLECTING DATA

All data – including pre-operative assessment, intra-operative data and post-operative questionnaires- will be collected on a paper Case Report File (see appendix) or recorded directly to an electronic CRF. Any paper CRFs will be de-identified and labelled with patient ID number and data will be transcribed to REDCAP database. All paper documents will be securely stored in a locked cabinet as per legal requirements. Paper documents will be destroyed 15 years post-study.

9.3. CASE REPORT FORMS AND SCHEDULE FOR COMPLETION

The Case Report Form will be provided in the appendix. The study is completed 7 days post-operation.

9.4. DATA FLOW

Protocol → CRF Design → Patient data collected in CRFs → Patient data in CRFs converted into raw data sets → Raw data sets → Create Tables/Listings/Figures → Create Analysis → Report

10. QUALITY CONTROL AND ASSURANCE

10.1. CONTROL OF DATA CONSISTENCY

All data will be collected by treating anaesthetic doctors (see CRF). Post-operative questionnaires will be provided to patients at 15 minutes post-operation, 24-hours post-operation and 7-days post-operation.

Data will be collected on paper CRFs and de-identified using patient id numbers. All data will be transcribed to REDCAP with permission to access only granted to study doctors and staff.

If feasible eCRFs will be used to ensure direct entry to improve efficiency and reduce entry errors, reduce data queries/missing data and maximise completed data.

10.2. PROTOCOL AMENDMENTS

All protocol amendments will be submitted to the HREC for approval prior to use. Trial centres will follow their local governance protocols to gain approval to commence this trial.

11. ETHICS

11.1. INVESTIGATOR AUTHORISATION PROCEDURE

Ethics and Governance approval will be obtained via the local HREC and governance offices prior to commencement of the study.

11.2. PATIENT PROTECTION

Research doctors and staff will ensure that the study is completed in accordance with the guidelines set out in the *National Statement on Ethical Conduct in Human Research* (2007) (the

National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and any other relevant legislation/guidelines.

12. SAFETY

12.1. ADVERSE EVENT REPORTING

Adverse event

The Australian Clinical Trial Handbook (*The Handbook*) defines an adverse event (drugs) as:

> any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of a medicinal (investigational/experimental) product, whether or not related to this product.[1]

Adverse drug reaction

The Handbook defines an adverse drug reaction as:

> For unapproved medicines: all noxious and unintended responses to a medicinal product related to any dose should be considered ADVERSE DRUG REACTIONS. The phrase "responses to a medicinal product" means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility.
>
> For marketed medical products: a response to a drug which is noxious and unintended and which occurs normally used in man for prophylaxis, diagnosis or therapy of diseases of for modification of physical function.[2]

Serious adverse event (SAE) or Serious Adverse Drug Reaction is defined as:

> Any untoward medical occurrence that at any dose:
>
> - results in death;
> - is life-threatening, (NOTE: The term 'life-threatening' in the definition of 'serious' refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an

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event/reaction which hypothetically might have caused death if it were more severe)

- requires in-patient hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect; or
- is a medically important event or reaction.[3]

The specific adverse events that will be monitored during this research project will be:

- Adverse reactions to dexmedetomidine – including allergic reactions
- Signs of Distress during the procedure: Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor
- Patient reported post-operative issues (as outlined in the satisfaction questionnaire – Case Report File- appendix 1)

Any adverse events will be noted in the Case Record File and transcribed to the RedCap Database.

Any adverse events or serious adverse events that compromises the ethical acceptability of the protocol will be reported to the local governance office as per policy.

12.2. SERIOUS ADVERSE EVENT REPORTING

All serious adverse events will be reported immediately to the sponsor and the HREC. The reports should be followed by a detailed written report. Follow-up reports should identify the participant/s by unique code assigned to participants (rather than by name).

12.3. DATA SAFETY AND MONITORING BOARD (DSMB)

Monitoring will be performed in accordance with GCP Monitoring guidelines and will be overseen by the DSMB which will include the following persons:

Prof Aeyal Raz (Israel)

Prof Jamie Sleigh (New Zealand)

Dr Amy Gaskell (New Zealand)

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[3]

The study site may be subject to monitoring at discretion of the DSMB – which may include review of de-identified material, consent for this by patients will be included in the PICF. Additional audits may be deemed necessary by the appointed head of the DSMB.

The DSMB will meet at three monthly intervals to review the trial activities.

12.4. EARLY TERMINATION

If early termination of the research project is required, the Principal Investigator Professor Robert Sanders will communicate with the HREC and Governance offices. All policies and procedures will be followed and documented.

13. BLINDING AND UNBLINDING

Subjects will receive either a dexmedetomidine or saline infusion. The anaesthetists will not be blinded to drug allocation.

14. CONFIDENTIALITY AND STORAGE AND ARCHIVING OF STUDY

Electronic data will be stored in a secured online database only accessible to those who are deemed to require access to the data for analysis purposes. Any staff who no longer require access to the online data will be removed from the database.

Paper CRFs will be kept in a locked secure file cabinet within the locked Department of Anaesthetics and keys will be kept in a safe location for those who require access. All documents will be held for 15 years as per legal requirements.

15. TRIAL FINANCING

Internal funding for this project will be provided through departmental resources

16. REFERENCES

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Appendices- Appendix 1: Case Report File

Pre-operative Data	
DOB and AGE at enrolment	
Sex	M F
ASA Status	
Height (meters)	
Body Weight (kg)	
BMI	
Surgical Operation	
Comorbid Diseases and Conditions	
Chronic medications (dose, last time taken)	
Beta Blockers	Yes No Drug: Dose: Time:
Benzodiazepine before Intubation:	Yes No Drug: Dose: Time:
History of Anaesthesia Awareness	
Preoperative Anxiety Scale (1-10)	
Preoperative Pain Scale (1-10)	

Baseline EEG

Baseline EEG Data Recorded?	Yes No
Time of Baseline recording:	0:00:00 -- _____
Eyes closed during baseline recording?	Yes No

Intra-operative Data **Date of Procedure:**

Commence EEG/Standard Monitor/Stop Watch recording		**TIME : : (24 hour clock)**
		0:00:00
Induction Commence		**TIME : :**
Induction drug administered:	**dose:**	**TIME : :**
Opioid drug administered:	**dose:**	**TIME : :**
Muscle relaxant administered	**dose:**	**TIME : :**
Continuous anesthesia started before intubation (either continuous IV infusion or the end tidal anesthetic concentration (ETAC) immediately before mask removal before intubation)		**YES/NO** **Time Start: : :**
OTHER DRUGS PRE-INTUBATION: **ETAC:**	**DOSES:**	**TIME : :**

PREINTUBATION COMMANDS (Immediately before intubation)	**IFT Testing Done Yes/No** **If no, why not:**
Tourniquet UP	**TIME : :**
Tourniquet DOWN	**TIME : :**
TOF **Response to TOF? Yes/No**	**TIME : :**

1. "X, squeeze my hand"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, if you are in pain squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
3. "X, if you are ok squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
Laryngoscopy commence			**TIME : :**
Endotracheal intubation			**TIME : :**
Spontaneous movements during laryngoscopy and intubation? (circle)	**Yes (description):**		**None**
Time to Intubate (circle):	**< 30 seconds**	**> 30 seconds**	
Estimated Duration of Laryngoscopy (seconds):			
Number of attempts at intubation:			

POSTINTUBATION COMMANDS (A) **(Within 10s of tube passing through cords).**		**IFT Testing Done Yes/No** **If no, why not:**	
Tourniquet UP		**TIME : :**	
Tourniquet DOWN		**TIME : :**	
TOF **Response to TOF? Yes/No**		**TIME : :**	
1. "X, birds fly north"			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			

Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, squeeze my hand" *"TABLE"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
3. "X, if you are in pain squeeze my hand two times" *"HAT"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
4. "X, if you are okay squeeze my hand two times" "*PENCIL*"			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
5. X, show me two fingers" *"LAMP"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
6. "X, if fish swim in the sea squeeze my hand" *"STOVE"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
7. "X, if stones float on water squeeze my hand" *"BASKET"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			

8. "X, squeeze my hand" ***"INDUSTRY", "OFFICE", "EGG", "JOURNAL"***			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
9. "X, squeeze my hand"			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			

POSTINTUBATION COMMANDS (B) **(Within 10s of tube passing through cords).**		**IFT Testing Done Yes/No** **If no, why not:**	
Tourniquet UP		**TIME : :**	
Tourniquet DOWN		**TIME : :**	
TOF **Response to TOF? Yes/No**		**TIME : :**	
1. "X, squeeze my hand"			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, birds fly north" ***"TABLE"***			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
3. "X, if you are in pain squeeze my hand two times" ***"HAT"***			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**

Notes			
4. "X, if you are okay squeeze my hand two times" *"PENCIL"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
5. X, show me two fingers" *"LAMP"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
6. "X, if fish swim in the sea squeeze my hand" *"STOVE"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
7. "X, if stones float on water squeeze my hand" *"BASKET"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
8. "X, squeeze my hand" **"INDUSTRY", "OFFICE", "EGG", "JOURNAL"**			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
9. "X, squeeze my hand"			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			

POSTINTUBATION COMMANDS (C) **(Within 10s of tube passing through cords).**		**IFT Testing Done Yes/No** **If no, why not:**	
Tourniquet UP		**TIME : :**	
Tourniquet DOWN		**TIME : :**	
TOF **Response to TOF? Yes/No**		**TIME : :**	
1. "X, bears walk south"			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, squeeze my hand" *"STREET"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
3. "X, if you are in pain squeeze my hand two times" *"TRUCK"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
4. "X, if you are okay squeeze my hand two times" *"BUTTER"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
5. X, show me two fingers" *"BOWL"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**

Notes			
6. "X, if sheep have wool, squeeze my hand" *"CLOCK"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
7. "X, if trees are made of glass, squeeze my hand" *"VIOLIN"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
8. "X, squeeze my hand" **"MATERIAL", "HISTORY", "FORK", "ENGINE"**			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
9. "X, squeeze my hand"			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			

POSTINTUBATION COMMANDS (D) **(Within 10s of tube passing through cords).**		**IFT Testing Done Yes/No** **If no, why not:**	
Tourniquet UP		**TIME : :**	
Tourniquet DOWN		**TIME : :**	
TOF **Response to TOF? Yes/No**		**TIME : :**	
1. "X, squeeze my hand"			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**

Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, bears walk south" *"STREET"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
3. "X, if you are in pain squeeze my hand two times" *"TRUCK"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
4. "X, if you are okay squeeze my hand two times" *"BUTTER"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
5. X, show me two fingers" *"BOWL"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
6. "X, if sheep have wool, squeeze my hand" *"CLOCK"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			
7. "X, if trees are made of glass, squeeze my hand" *"VIOLIN"*			**TIME : :**
RESPONSE (circle)	**Definite**	**Indeterminate**	**None**
Notes			

8. "X, squeeze my hand" **"MATERIAL", "HISTORY", "FORK", "ENGINE"**		**TIME : :**
RESPONSE (circle)	**Definite Indeterminate None**	
Notes		
9. "X, squeeze my hand"		**TIME : :**
RESPONSE (circle)	**Definite Indeterminate None**	
Notes		

SURGICAL INCISION **IFT Testing Done Yes/No** **If no, why not:**			
Time of Incision		**TIME : :**	
Tourniquet UP		**TIME : :**	
Tourniquet DOWN		**TIME : :**	
TOF		**TIME : :**	
Response to TOF? Yes/No			
1. "X, squeeze my hand"		**TIME : :**	
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, if you are in pain squeeze my hand two times"		**TIME : :**	
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

3. "X, if you are ok squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

DURING SURGERY (30 minute intervals)		**IFT Testing Done**	**Yes/No**
If no, why not:			
Tourniquet UP		**TIME**	**: :**
Tourniquet DOWN		**TIME**	**: :**
TOF		**TIME**	**: :**
Response to TOF? Yes/No			
1. "X, squeeze my hand"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, if you are in pain squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
3. "X, if you are ok squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

<u>Start Emergence (End Anesthetic)</u>		**IFT Testing Done Yes/No**	
If no, why not:			
End Anesthetic		**TIME : :**	
Tourniquet UP		**TIME : :**	
Tourniquet DOWN		**TIME : :**	
TOF		**TIME : :**	
Response to TOF? Yes/No			
1. "X, squeeze my hand"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anaesthesia monitor):			
2. "X, if you are in pain squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
3. "X, if you are ok squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

0.2 MAC Emergence	**IFT Testing Done**	**Yes/No**	
If no, why not:			
0.2 MAC		**TIME**	**: :**
Tourniquet UP		**TIME**	**: :**
Tourniquet DOWN		**TIME**	**: :**
TOF		**TIME**	**: :**
Response to TOF? Yes/No			
1. "X, squeeze my hand"		**TIME**	**: :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, if you are in pain squeeze my hand two times"		**TIME**	**: :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
3. "X, if you are ok squeeze my hand two times"		**TIME**	**: :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

Emergence Important Times		
First Swallow	**Time:**	**: :**

First Spontaneous Hand Movement	**Time: : :**
Eyes Open	**Time: : :**
Extubation	**Time: : :**
First Response to Command Upon Emergence	**Time: : :**
Procedure End	**Time: : :**
Anesthesia End (arrival to PACU)	**Time: : :**

Time EEG Recording End (24 hour clock):

Total Length of EEG Recording:

Additional IFT Testing:

Time Point:	**IFT Testing Done Yes/No**		
Tourniquet UP	**TIME: : :**		
Tourniquet DOWN	**TIME: : :**		
TOF **Response to TOF? Yes/No**	**TIME : :**		
1. "X, squeeze my hand"	**TIME : :**		
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, if you are in pain squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
3. "X, if you are ok squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

Time Point:		**IFT Testing Done**	**Yes/No**
Tourniquet UP		**TIME:**	**: :**
Tourniquet DOWN		**TIME:**	**: :**
TOF		**TIME**	**: :**
Response to TOF? Yes/No			
1. "X, squeeze my hand"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, if you are in pain squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None

Notes			
3. "X, if you are ok squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

Time Point:		**IFT Testing Done**	**Yes/No**
Tourniquet UP		**TIME:**	**: :**
Tourniquet DOWN		**TIME:**	**: :**
TOF		**TIME**	**: :**
Response to TOF? Yes/No			
1. "X, squeeze my hand"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, if you are in pain squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
3. "X, if you are ok squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

Time Point:		**IFT Testing Done**	**Yes/No**
Tourniquet UP		**Time:**	**: :**
Tourniquet DOWN		**Time:**	**: :**
TOF		**TIME**	**: :**
Response to TOF? Yes/No			
1. "X, squeeze my hand"		**TIME**	**: :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, if you are in pain squeeze my hand two times"		**TIME**	**: :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
3. "X, if you are ok squeeze my hand two times"		**TIME**	**: :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

Time Point:		**IFT Testing Done**	**Yes/No**
Tourniquet UP		**Time:**	**: :**
Tourniquet DOWN		**Time:**	**: :**
TOF		**TIME**	**: :**
Response to TOF? Yes/No			
1. "X, squeeze my hand"		**TIME**	**: :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, if you are in pain squeeze my hand two times"		**TIME**	**: :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
3. "X, if you are ok squeeze my hand two times"		**TIME**	**: :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

Time Point:	**IFT Testing Done**	**Yes/No**
Tourniquet UP	**Time:**	**: :**
Tourniquet DOWN	**Time:**	**: :**
TOF	**TIME**	**: :**

Response to TOF? Yes/No			
1. "X, squeeze my hand"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, if you are in pain squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
3. "X, if you are ok squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

Time Point:	**IFT Testing Done**	**Yes/No**
Tourniquet UP	**Time:**	**: :**
Tourniquet DOWN	**Time:**	**: :**
TOF	**TIME**	**: :**
Response to TOF? Yes/No		
1. "X, squeeze my hand"		**TIME : :**
RESPONSE (circle)	Definite	Indeterminate None
Notes		

Signs of Distress /Arousal (Pupils, Sweating, Tachycardic, Hypertension, Change in Depth of Anesthesia monitor):			
2. "X, if you are in pain squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			
3. "X, if you are ok squeeze my hand two times"			**TIME : :**
RESPONSE (circle)	Definite	Indeterminate	None
Notes			

Post-operative Data **Date of Assessment:**_____

15 minutes after arrival to PACU- Time:_____

RASS Score	
Nu-DESC Score	
Anxiety Scale (1-10)	
Pain Scale (1-10)	
PONV Score (0-none, 1- nausea, 2-vomiting)	

CAM-ICU 7

CAM-ICU		
Items	**Grading**	**Score**
1. Acute Onset or Fluctuation of Mental Status Is the patient different than his/her baseline mental status? OR Has the patient had any fluctuation in mental status in the past 24 hours as evidenced by fluctuation on a sedation/level of consciousness scale (i.e., RASS/SAS), GCS, or previous delirium assessment?	0 absent 1 present	
2. Inattention Say to the patient, "*I am going to read you a series of 10 letters. Whenever you hear the letter 'A,' indicate by squeezing my hand.*" Read letters from the following letter list in a normal tone 3 seconds apart. SAVEAHAART (Errors are counted when patient fails to squeeze on the letter "A" and when the patient squeezes on any letter other than "A")	0 absent (correct ≥ 8) 1 for inattention (correct 4-7) 2 for severe inattention (correct 0-3)	
3. Altered Level of Consciousness Present if the Actual RASS score is anything other than alert and calm (zero)	0 absent (RASS 0) 1 for altered level (RASS 1, −1) 2 for severe altered level (RASS >1, < −1)	
4. Disorganized Thinking Yes/No Questions 1. Will a stone float on water? 2. Are there fish in the sea? 3. Does one pound weigh more than two pounds? 4. Can you use a hammer to pound a nail? Errors are counted when the patient incorrectly answers a question. Command: Say to patient "Hold up this many fingers" (Hold two fingers in front of patient). "Now do the same with the other hand" (Do not repeat number of fingers) An error is counted if patient is unable to complete the entire command.	0 absent (correct ≥ 4) 1 for disorganized thinking (correct 2, 3) 2 for severe disorganized thinking (correct 0, 1)	
	Total Score	

60 minutes after arrival to PACU- Time: _____

RASS Score	
Nu-DESC Score	
Anxiety Scale (1-10)	
Pain Scale (1-10)	
PONV Score (0-none, 1-nausea, 2-vomiting)	

CAM-ICU 7

CAM-ICU		
Items	**Grading**	**Score**
1. Acute Onset or Fluctuation of Mental Status Is the patient different than his/her baseline mental status? OR Has the patient had any fluctuation in mental status in the past 24 hours as evidenced by fluctuation on a sedation/level of consciousness scale (i.e., RASS/SAS), GCS, or previous delirium assessment?	0 absent 1 present	
2. Inattention Say to the patient, "*I am going to read you a series of 10 letters. Whenever you hear the letter 'A,' indicate by squeezing my hand.*" Read letters from the following letter list in a normal tone 3 seconds apart. SAVEAHAART (Errors are counted when patient fails to squeeze on the letter "A" and when the patient squeezes on any letter other than "A")	0 absent (correct ≥ 8) 1 for inattention (correct 4-7) 2 for severe inattention (correct 0-3)	
3. Altered Level of Consciousness Present if the Actual RASS score is anything other than alert and calm (zero)	0 absent (RASS 0) 1 for altered level (RASS 1, −1) 2 for severe altered level (RASS >1, < −1)	
4. Disorganized Thinking Yes/No Questions 1. Will a stone float on water? 2. Are there fish in the sea? 3. Does one pound weigh more than two pounds? 4. Can you use a hammer to pound a nail? Errors are counted when the patient incorrectly answers a question. Command: Say to patient "Hold up this many fingers" (Hold two fingers in front of patient). "Now do the same with the other hand" (Do not repeat number of fingers) An error is counted if patient is unable to complete the entire command.	0 absent (correct ≥ 4) 1 for disorganized thinking (correct 2, 3) 2 for severe disorganized thinking (correct 0, 1)	
	Total Score	

Nu-DESC:

Features and Descriptions	Symptoms Rating (0-2)	
Time Period / Symptom	15 minutes after admission into PACU	60 minutes after admission into PACU
I. Disorientation Verbal or behavioral manifestation of not being oriented to time or place or misperceiving persons in the environment • **Last name? Location? Year? Why here?**		
II. Inappropriate Behavior Behavior inappropriate to place and/or for the person; e.g. puling at tubes or dressings, attempting to get out of bed when that is contraindicated, and the like.		
III. Inappropriate Communication Communication inappropriate to place and/or for the person; e.g., incoherence, non-communicativeness, nonsensical or unintelligible speech.		
IV. Illusions/Hallucinations Seeing or hearing things that are not there; distortions of visual objects. • **In the last few minutes, have you seen or heard things that are not really there?** • **Is your vision or hearing distorted?**		

V. Psychomotor retardation Delayed responsiveness, few or no spontaneous actions/words; e.g., when the patient is prodded, reaction is deferred and/or the patient is unarousable.		
Total Score		

GUIDELINES TO SCORING:

DISORIENTATION:

0 = No signs of item present. Patient is orientated to time place and person.
1 = Mild to moderate, barely expressed and noticeable through to being present and undeniable. Patient still can provide some orientating information to time, place and/or person.
2 = Moderate to severe: patient is not orientated to time or place. I,e in severe impairment will be not able to tell you the date, month, day, year, season, floor, name of hospital, city, state, and country.

INAPPROPRIATE BEHAVIOUR:

0 = no signs of item present
1 = mild to moderate: Hyperactivity is barely noticeable or appears as simple restlessness, to undeniable, subject moves frequently.
2 = moderate to severe: Hyperactivity is severe; patient is constantly moving, overreacts to stimuli, requires surveillance and/or restraint

INAPPROPRIATE COMMUNICATION;

0 = no sign of items present: patient's speech is coherent and goal-directed
1 = mild to moderate: patient's speech is slightly difficult to follow; responses to questions are slightly off target, to disorganized speech being clearly present
2 = moderate to severe: conversation is impossible due to severely disorganized thinking or speech (e.g rambling, irrelevant, or incoherent speech, or by tangential, circumstantial, or faulty reasoning)

ILLUSIONS/HALLUCINATIONS:

0 = no sign of items present
1 = mild to moderate: misperceptions or illusions related to sleep, fleeting hallucinations
2 = moderate to severe: frequent or intense illusions or hallucinations that disrupts care, function or is associated with inappropriate behaviour.

PSYCHOMOTOR RETARDATION:

0 = no sign of items present
1 = mild to moderate: Hypoactivity is barely noticeable, expressed as slightly slowing of movement, to moderate slowing of movements.
2 = moderate to severe: Hypoactivity is severe; patient does not move or speak without prodding or is catatonic

24-Hour Post-operative Follow Up

Date of follow up: _____ *Time of follow up: _____*

At any stage after the operation, did you have the following (please check one box for each question 1-10):

	No	Yes, Moderate	Yes, Severe
1. Drowsiness	☐	☐	☐
2. Pain at the site of surgery	☐	☐	☐
3. Thirst	☐	☐	☐
4. Hoarseness	☐	☐	☐
5. Sore throat	☐	☐	☐
6. Nausea or vomiting	☐	☐	☐
7. Feeling cold	☐	☐	☐
8. Confusion or disorientation	☐	☐	☐
9. Pain at the site of the anesthetic injection	☐	☐	☐
10. Shivering	☐	☐	☐

	Very Satisfied	Satisfied	Dissatisfied	Very Dissatisfied	N/a
11. How satisfied were you with the information you were given by the anesthetist before the operation?					
12. How satisfied were you waking up from anesthesia?					
13. How satisfied have you been with pain therapy after surgery?					
14. How satisfied were you with treatment of nausea and vomiting after the operation?					
15. How satisfied were you with the care provided by the department of anesthesia in general?					

16. Would you recommend this anesthetic service to friends and family?	Yes ☐	No ☐

17. What is the last thing you remember before going to sleep (please check one box)?

☐	Being in the pre-operative area
☐	Seeing the operating room
☐	Being with family
☐	Hearing voices
☐	Feeling mask on face
☐	Smell of gas
☐	Burning or stinging in the IV line
☐	Other:

18. What is the first thing you remember after waking up (please check one box)?

☐	Hearing voices
☐	Feeling breathing tube
☐	Feeling mask on face
☐	Feeling pain
☐	Seeing the operating room
☐	Being in the recovery room
☐	Being with family
☐	Being in the intensive care unit
☐	Nothing
☐	Other:

19. Do you remember anything between going to sleep and waking up (please check <u>ALL</u> relevant boxes)?

☐	No
☐	Yes; Hearing voices
☐	Yes; being asked to squeeze the hand of the research staff
☐	Yes; Hearing events of the surgery
☐	Yes; being unable to move or breathe
☐	Yes; anxiety/stress
☐	Yes; feeling pain
☐	Yes; Sensation of breathing tube
☐	Yes; Feeling surgery without pain
☐	Yes; Other:

20. Did you dream during your procedure (please check one box)?

☐	No
☐	Yes; Please describe:

21. Were these dreams disturbing to you (please check box)?	Yes ☐ No ☐

22. What was the worst thing about your operation (please check one box)?

☐	Anxiety
☐	Pain
☐	Recovery Process
☐	Unable to carry out usual activities
☐	Awareness
☐	Other:

Thank you for taking the time to complete this questionnaire.

7-Day Post-operative Follow-Up

Date of follow up: _____ *Time of follow up:* _____

At any stage after the operation, did you have the following (please check one box for each question 1-10):

	No	Yes, Moderate	Yes, Severe
1. Drowsiness	☐	☐	☐
2. Pain at the site of surgery	☐	☐	☐
3. Thirst	☐	☐	☐
4. Hoarseness	☐	☐	☐
5. Sore throat	☐	☐	☐
6. Nausea or vomiting	☐	☐	☐
7. Feeling cold	☐	☐	☐
8. Confusion or disorientation	☐	☐	☐
9. Pain at the site of the anesthetic injection	☐	☐	☐
10. Shivering	☐	☐	☐

	Very Satisfied	Satisfied	Dissatisfied	Very Dissatisfied	N/a
11. How satisfied were you with the information you were given by the anesthetist before the operation?					
12. How satisfied were you waking up from anesthesia?					
13. How satisfied have you been with pain therapy after surgery?					
14. How satisfied were you with treatment of nausea and vomiting after the operation?					
15. How satisfied were you with the care provided by the department of anesthesia in general?					

16. Would you recommend this anesthetic service to friends and family?	Yes ☐	No ☐

17. What is the last thing you remember before going to sleep (please check one box)?

☐	Being in the pre-operative area
☐	Seeing the operating room
☐	Being with family
☐	Hearing voices
☐	Feeling mask on face
☐	Smell of gas
☐	Burning or stinging in the IV line
☐	Other:

18. What is the first thing you remember after waking up (please check one box)?

☐	Hearing voices
☐	Feeling breathing tube
☐	Feeling mask on face
☐	Feeling pain
☐	Seeing the operating room
☐	Being in the recovery room
☐	Being with family
☐	Being in the intensive care unit
☐	Nothing
☐	Other:

19. Do you remember anything between going to sleep and waking up (please check <u>ALL</u> relevant boxes)?

☐	No
☐	Yes; Hearing voices
☐	Yes; being asked to squeeze the hand of the research staff
☐	Yes; Hearing events of the surgery
☐	Yes; being unable to move or breathe
☐	Yes; anxiety/stress
☐	Yes; feeling pain
☐	Yes; Sensation of breathing tube
☐	Yes; Feeling surgery without pain

☐	Yes; Other:

20. Did you dream during your procedure (please check one box)?

☐	No
☐	Yes; Please describe:

21. Were these dreams disturbing to you (please check box)?	Yes ☐ No ☐

22. What was the worst thing about your operation (please check one box)?

☐	Anxiety
☐	Pain
☐	Recovery Process
☐	Unable to carry out usual activities
☐	Awareness
☐	Other:

Thank you for taking the time to complete this questionnaire.

Appendix 2:

Pre-operative Questionnaire for Females

1) What is your current contraception if any?

[ ] None

[ ] Fertility awareness /withdrawal method

[ ] Condoms/cap/diaphragm

[ ] Combine oral contraceptive pill*

[ ] Progesterone only pill*

[ ] Contraceptive implant (implanon/Nexplanon)

[ ] Contraceptive intrauterine device (non hormonal)

[ ] Contraceptive intrauterine device (hormonal)

[ ] Sterilisation

*If you take a contraceptive pill have you missed any pills in the last week? Yes/No

2) Do you take any form of hormone therapy or replacement? Yes/No

Please specify medication:

3) Do you have regular periods? (please tick one box)
- Yes
- No, they have never been regular
- No, they have been irregular for a few months
- No, my periods have stopped

4) What is the usual interval between the start of one period and the start of your next period (cycle length)? _____days

5) How long do your periods usually last for? _____days

6) When was your last period? Please fill in the date of the first day of your last period (dd/mm/yy)

7) If you your periods have stopped, what best describes the reason you have not had a period in the last 12 months? (please tick one box)
- Menopause
- Currently pregnant
- Currently breast feeding
- Contraceptives e.g. hormonal IUD, contraceptive implants
- Medical e.g. medication, chemotherapy, radiotherapy
- Surgical e.g. uterus removed, ovaries removed, ablation (novasure)
- Other: please describe_____