Clinical Trial Informed consent for patients undergoing "Total Knee Arthroplasty"

This Informed Consent Form is for men and women who will undergo Total knee arthroplasty under regional anesthesia.

- **Title of the study: Efficacy of peri-operative oral Investigational drug (ID) use on pain after total knee replacement:**

- **NHRA clinical trial approval code: PH4-NHRA24-04 No: M R U /90-2024/ S M H**

- **Names and affiliations of the principal investigator: Dr. Mehtash butt**, Chief resident anesthesia /ICU: Dr. Jalal alkhan Consultant HOD anesthesia/ICU

- **Sponsor of the study:** Bahrain defence forces hospital.

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet:

*I am **Dr. Mehtash Butt**, the Chief Resident in Anesthesia/ICU at Bahrain Defense Forces Hospital. Our current **research focuses on investigating the impact of ID during operation on pain following total knee arthroplasty, a procedure known to cause moderate to severe pain**. I would like to provide you with information regarding this research and extend an invitation for you to participate. You are not required to make a decision today regarding your participation. Feel free to discuss the research with anyone you trust before reaching a decision.*

If there are any unfamiliar terms or concepts during our discussion, please feel free to ask for clarification. I will take the time to explain. Additionally, if you have any questions later on, you can direct them to me, the study doctor, or the staff involved in the research.

Subject selection criteria: All patients scheduled for Total Knee Arthroplasty

Purpose of the research:

This study is a clinical trial
To assess effects of **Investigational Drug** in reducing pain and decreasing requirements of other pain killers after knee surgery.
This trial will continue for 18-24 months but your participation is required for the duration of your stay in hospital after surgery i.e. 72 Hrs (anticipated).
You understand the process of assignment of sample/Patient and the fact that you might/might not be in drug group but you'll receive the stand medical care.

Type of research intervention: Oral Cap/Tab of investigational Drug with be prescribed at the time of admission, only patients assigned to drug group will receive the medication.

Procedure and protocol:

Before surgery you will receive Treatment as per group assignment.
In the operation theatre you will receive injection to relieve your anxiety & spinal anesthesia i.e. Injection in your back to numb your legs. You will receive **Ultrasound guided Adductor canal saphenous Nerve block in your leg in the recovery area**.

Adductor canal block: It is type of regional anesthesia of the leg which will be done in recover care unit, you will not feel pain as you will still be under effect of spinal anesthesia. This is to prolong the analgesic effect of local anesthetics.
After operation you will receive standard medical care in the ward which we provide to all patients. You may or may not receive investigational drug.

Risks and discomforts:

This ID is anticipated to reduce postoperative pain and there are potential risks associated with participating in this study, including but not limited to:

ID side effects include:
>10%
Dizziness, Sleepiness, peripheral swelling, imbalance, fatigue, trembling hands.
1-10%
Lack of strength (Asthenia), swelling, facial swelling, low BP, confusion.
<1%
Addiction, diarrhea, anemia, heart failure.

By participating in this research it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your pain will not get better and that the new medicine doesn't work even. If, however, the medicine is not working and your pain does not go down in 24 hours we will give you stronger pain killers which will bring your pain down and make you more comfortable.

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with pain killers. (also standard of protocol)

Benefits:

The primary objective of this study is to explore the potential impact of ID on reducing the dependence on opioids by anesthetists for managing acute pain. Furthermore, this research endeavour holds the potential to enhance our understanding of the interactions between medications in the context of pain management, benefiting both society and the field of science.
I understand that I may not benefit directly from the research.

Alternatives:

This investigational drug is just an addition to standard medical care. If I don't participate I'll receive the standard pain management given to all patients routinely.

Confidentiality:

All collected data and personal information during this clinical trial will be handled with utmost confidentiality and will only be accessible to authorized personnel for research purposes, ensuring the privacy and anonymity of participants. **You understand and consent** that data will only be kept confidential to the extent permitted by law.

Cost and compensation

Participating in this trial will not impose any financial burden on you, including those who are not sponsored or insured. It is important to note that there will be no compensation provided for taking part in this research study.

Research questions

Please contact following personals for answers to pertinent questions about the research and participant's rights and in the event of a research-related injury to the participant.

i Contact information of the principal investigator : Dr. Mehtash butt Chief resident anesthesia/ICU BDF hospital Mob: 36681277 , dr.mehtashbutt@yahoo.com

ii Contact information of the IRB/IEC : Ms saleha research coordinator and sec. to director,33374551, saleha.gulam@bdfmedical.org

iii Contact information of NHRA representative : 17113340, ct@nhra.bh

Voluntary participation

I have been informed that there may be no direct benefits from participating in this study. However, I believe that my **Volunteer participation** may contribute to the advancement of medical knowledge and potentially benefit future patients with similar conditions.

Clinically relevant research results

I'll be informed about the medically significant results of the trial.

Publicly available information

The Randomized Clinical Trial, "Effect of perioperative Pregabalin in Total knee Arthroplasty postoperative pain", will be available on https://www.anzctr.org.au , as required by NHRA CT Regulations. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time."

Consent discussion

I have read (or had read to me) this consent form thoroughly and have been encouraged to seek clarification by asking any questions. All of my questions have been answered to my satisfaction. I acknowledge that my participation in this research study is entirely voluntary and that I retain the right to withdraw from the study at any time without facing any negative consequences. Furthermore, you confirm that you are above the age of 21 and willingly consent to participate in this research study.

Possibility of unforeseeable risks:

All risks has been explained.

Potential termination without regard to consent:
You are informed that if regional anesthesia is ineffective and converted to general anesthesia, your participation in the trial may be discontinued as it falls under the exclusion criteria.

BDF ROYAL MEDICAL SERVICES

Patient Consent for Research Participation & Publication of Materials in BDFRMS

The following information must be provided for this form to be processed accurately.

NHRA CTR code: **PH4-NHRA24-04 No: M R U /90-2024/ S M H**
Title: Effect of perioperative Investigational Drug ID in Total knee Arthroplasty postoperative pain.
Author(s): Dr. Mehtash butt: Chief resident anesthesia/icu, Dr. Jalal, HOD anesthesia/ICU

Patients scheduled for Total knee replacement are enrolled and they have the right to refuse to sign this consent forum; refusal to sign this form will not affect their care in anyway

I understand that there are potential risks associated with participating in this study. I have been explained about all the risk and benefits of the medication under study i.e. ID.,

I hereby give my consent for images or other clinical information relating to my case to be used by BDF Royal Medical Services

I understand that my name and initials will not be published and that efforts will be made to conceal my identity, but that anonymity cannot be guaranteed, also that the material may be utilized by BDFRMS. As a result, I understand that the material may be seen by the general public. I understand that the material may be included in medical books published by IN House Training.

_____
Name of the Patient

Patient's date of Birth _____

_____
Signature of patient (or signature of the Person giving consent on behalf of the patient)

Date: _____

_____
If you are not the patient, what is your relationship to him or her? (The person giving consent should be a substitute decision maker or legal guardian or should hold power of attorney for the patient)

_____
Why is the patient not able to give consent? (e.g.; is the patient a minor, incapacitated, or deceased?)

If images of the patient's face or distinctive body markings are to be published, the following section should be signed in addition to the first section:

I give permission for images of my face or distinctive body markings to be published and recognize that I might therefore be identifiable even though my name and initials will not be published.

_____
Signature of patient (or signature of the persons giving Consent on behalf of the patient)

Date: _____

Please complete all required fields (file number, title and author) before returning to: PO. Box 28743, Riffa or by mail: training.directorate@bdfmedical.org or fax: 17766822

Case report form:

Effect of Perioperative oral pregabalin in Total Knee replacement for postoperative pain.

Serial N0: _____ Hospital Record NO: _____

Date: _____ Patient Age: _____

Gender: _____ ASA Status: _____

Preoperative Oral capsule pregabalin time: _____.

Subarachnoid block given (Bupivacain+fentanyl) (Start point time) _____

Postoperative USG guided femoral nerve block (Bupivacaine + dexmedetomidine): start point time. _____

VAS SCORE: (0-10)

Time:Start point	At 4Hrs	8Hrs	12Hrs	24Hrs
	36 Hrs	48Hrs	60Hrs	72Hrs

Sedation score: RASS attached {0- (-5)}

+4	+3	+2	+1	0	-1	-2	-3	-4	-5

Time:Start point	At 4Hrs	8Hrs	12Hrs	24Hrs
	36 Hrs	48Hrs	60Hrs	72Hrs

VAS at 1st CPM : _____

Time of 1st analgesia request:_____

Incident of bradycardia in 1st 24 Hrs: Y/N _____

Incident of Hypotension in 1st 24 Hrs: Y/N _____

Incident of PONV in 1st 24 Hrs: Y/N _____

Total opioid consumption in 72hrs: Oxycodone: _____mg Morphine: _____ mg.

Patient satisfaction (1-5): at 72 Hrs(1: Not satisfied, 5: fully satisfied)

1	2	3	4	5