**Participant Information Sheet/Consent**

**STUDY TITLE:** A single-blinded randomised trial evaluating the efficacy of chitosan-dextran (Chitodex) gel with topical steroid versus PureRegen gel on post-operative outcomes in the treatment of Chronic Rhinosinusitis (CRS)

**SHORT TITLE:** Effects of Chitodex with steroid on patients having sinus surgery for chronicrhinosinusitis

**INVESTIGATORS:**

Coordinating Principal Investigator:
**Associate Professor Yuresh Naidoo**
Macquarie University Hospital, Concord Repatriation General Hospital, North Shore Private, Sydney Adventist Hospital, Campbelltown Private Hospital, Auburn Hospital, and The ENT Centre.
Co-Investigators:

**Professor Raymond Sacks**

Sydney University, Macquarie University, Macquarie University Hospital, Concord Repatriation General Hospital, North Shore Private, Sydney Adventist Hospital, Campbelltown Private Hospital, Auburn Hospital, and The ENT Centre.

**Dr Arjuna Ananda**

Macquarie University Hospital, Concord Repatriation General Hospital, North Shore Private, Sydney Adventist Hospital, Campbelltown Private Hospital, Auburn Hospital, and The ENT Centre.

**PROJECT SPONSOR:** This is an investigator-initiated study and will be undertaken with support from The ENT Centre – a private specialist practice. All of the above investigators are affiliated with the ENT Centre and their listed places of work.

**CONFLICTS OF INTEREST:**

Professor Peter-John Wormald at The Department of Otolaryngology, Head and Neck Surgery, The University of Adelaide is a shareholder of Chitogel Ltd and he will be supplying the Chitodex kits used in this study.

**INTRODUCTION:**

You are invited to take part in a research study called a clinical trial. Clinical trials are research studies where people volunteer to test new treatments or tests to prevent, detect, treat or manage various diseases or medical conditions. You are invited to participate in this clinical trial because you have chronic sinusitis and you are about to undergo surgery for it.

This clinical trial is looking to improve the care you receive after your endoscopic sinus surgery (ESS). We wish to compare a new absorbable sinus gel dressing (called Chitodex) to the absorbable sinus gel dressing that we currently use (called PureRegen). We will look at these gels to see which one shows improved healing after sinus surgery.

Before you decide to take part, this information sheet will tell you about what is involved in the study and why we are doing it. You do not have to make an immediate decision. Please read this information sheet carefully. If there is anything you do not understand or if you feel you need more information about, please ask. Before you decide, please feel free to talk things over with a relative, a friend or your own doctor. Your decision to take part, or not to take part, will have no effect on your relationship with your ENT surgeon or the hospital.

Chronic rhinosinusitis affects about 15% of the general population and is characterised by sinusitis symptoms continuing for more than 3 months. Patients who do not respond to oral and topical steroids, antibiotics and nasal rinsing require surgical management. The surgical procedure is called endoscopic sinus surgery (ESS), and involves removing inflamed tissue and mucus, as well as clearance of bony walls within the sinus cavity to open up blocked areas. You will receive the standard hospital and surgical information sheet about the sinus surgery, and you will sign the standard hospital consent form for the sinus surgery.

The purpose of this trial is to test two absorbable sinus gel dressings to see whether Chitodex gel (including a topical steroid, triamcinolone) shows improved wound-healing compared to our standard current dressing (PureRegen gel). A total of 31 participants will be recruited to this trial.

**VOLUNTARY PARTICIPATION:**

Taking part in this trial is entirely voluntary. You do not have to take part in it. You will receive the best possible care whether or not you are part of this trial.

**STUDY PROCEDURES:**
If you agree to participate in this study, you will be asked to sign the Participant Consent Form at the end of this form. You will then undergo the planned endoscopic sinus surgery (ESS). Following the ESS, the following procedures will occur:

* At the end of the ESS procedure, before you wake up, the surgeon will apply 10 ml of the new sinus gel (Chitodex + steroid) into one side of your sinus cavity and 10ml of the current sinus gel (PureRegen) into the other side of your sinus cavity. This will take less than 10 minutes.
* The care you will receive after your surgical procedure will include the standard care after sinus surgery being 10 days of oral antibiotics, nasal flushing with saline and then nasal flushing with a steroid solution (Pulmicort ®) after 2 weeks (first visit after surgery).
* You will return to the ENT Centre at 2 weeks, 6 weeks, and 12 weeks after the surgery for ongoing review (this is standard for this type of surgery). During each visit, you will be asked to complete a symptom questionnaire for the study, and we will perform the standard endoscopic examination of your sinuses using an endoscopic camera. During this examination, we will take measurements of your sinus openings for the study, using a small ball probe for scale. The endoscopic camera can record the examination, and this will be recorded each time for the study. The videos will have your name removed and viewed by another surgeon, who will not know which gel dressing has been applied to which side of your nose.
* The questionnaire and video recording will add less than 10 minutes to each appointment visit.
* The recorded video examination will be scored for infection (pus), swelling, inflammation, and crusting using a standardised scoring scale.

This table details the standard of care (after ESS) procedures which you will have, and the additional study-related procedures.

| **Visit** | **Standard of Care Procedures** | **Study-Related Procedures** |
| --- | --- | --- |
| 0. Recruitment into the study |  | Symptom questionnaire |
| 1. Sinus surgery | Endoscopic sinus surgery  | Endoscopic video recording |
| Application of PureRegen gel to the sinuses; left and right | Application of Chitodex steroid gel to one side (left and right sides of your sinuses are randomly selected by a computer to receive one of each type of gel) |
| Oral antibiotics – 10 days, and |  |
| Saline nasal flushing – 4 times per day for 2 weeks |  |
| 2. 2 weeks post-surgery follow-up visit 1 | Return to clinicEndoscopic examination and clean | Endoscopic video recordingSymptom questionnaire |
| Pulmicort® nasal flushing – 1 times per day |  |
| 3. 6 weeks post-surgery follow-up visit 2 | Return to clinic Endoscopic examination | Endoscopic video recordingSymptom questionnaire |
| 4. 12 weeks post-surgery follow-up visit 3 | Return to clinicEndoscopic examination | Endoscopic video recordingSymptom questionnaire |

**COSTS:**

You (or your health insurer) will pay for your surgery and the standard of care medications; antibiotics, saline rinses and Pulmicort rinses. Participation in the study will not cost you anything, nor will you be paid. The investigators will supply the nasal dressings as part of the study.

**WHAT ARE THE BENEFITS OF TAKING PART?**

While we intend that this research study furthers medical knowledge and may improve treatment of chronic rhinosinusitis in the future, it may not be of direct benefit to you.Possible benefits may include better healing.

**WHAT ARE THE RISKS OF TAKING PART?**

The risks of sinus surgery have been explained to you by your ENT surgeon.

The Australian Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods. PureRegen gel is approved by the TGA as a Class 1a medical device so it can be lawfully supplied in Australia.

The risks of participating in this study are very low.

We expect no local or systemic issues from the application of Chitodex gel including triamcinolone as both of these products have been used in humans before.

The possible risks associated with application of the gels are listed below:

|  |  |  |
| --- | --- | --- |
| Possible Risk/Side Effect | When this may occur? | How often this may occur? |
| Topical allergy to the Chitodex gel | Within 24 hours after your surgery | Once |
| Foreign body reaction (inflammation) | Within 1 to 7 days after your surgery | Once |

We will place the gels deep into your sinus passages so you should be able to breathe as normal, through your nose. However, due to the effects of the surgery (inflammation and the healing processes), you may have a blocked nose after surgery.

In other published trials involving the use of Chitodex as a topical product in human subjects, there have been no reported adverse events.

There may be side effects that the researchers do not expect or do not know about. Tell your study doctor immediately about any new or unusual symptoms that you experience. Your study doctor will discuss the best way of managing any side effects with you. The general drug allergy symptoms to watch for are skin rashes, itching, burning sensation in throat and stomach, vomiting or bleeding from the nose.

Chitodex with topical triamcinolone are not approved for use in Australia by the TGA and are not listed on the Australian register of Therapeutic Goods (ARTG). The Australian Register of Therapeutic Goods is a register of therapeutic goods that can be lawfully supplied in Australia.

The researchers will submit a Clinical Trial Notification (CTN) to the TGA, which allows them to use Chitodex in Australia for medical research purposes based on assessment and approval by an appropriately constituted Human Research Ethics Committee.

**PREGNANCY & BREASTFEEDING:**

The effects of Chitosan gel and steroids on the unborn child and on the newborn baby are not known. Because of this, it is important that trial participants are not pregnant or breastfeeding at the time of surgery and application of gel.

## IF NEW INFORMATION BECOMES AVAILABLE

Sometimes, during the course of a study, new information becomes available about the treatment that is being studied. While you are participating in the study you will be kept informed of any significant new findings that may affect your willingness to continue in the study.

**COMPENSATION FOR INJURIES OR COMPLICATIONS**

If you suffer any injuries or complications as a result of this study, you should contact the study team on (02) 9476 1919 as soon as possible. They will assist you in arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. Your participation in this study does not affect any other right you may have to compensation under common law.

**WITHDRAWAL**

You are free to withdraw at any time, for any reason, during the study without affecting your future health care. Please advise one of the Investigators if you wish to do so. You may also request that your research-related data be permanently deleted.

## DATA & CONFIDENTIALITYThe pooled results of this trial will be published in a scientific journal. You will not be identifiable.

All the information collected about you during this trial will be treated confidentially. The Sydney Local Health District (SLHD) software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of research data. REDCap is a secure, web-based, non-commercial, data management tool designed for research purposes. Data collected by REDCap is stored on servers in the SLHD data centre. Data is secured, and back-up, privacy and confidentiality considerations are protected by standard ICT practices.

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using information about you for the research project. Any information obtained in connection with this research project that can identify you (e.g.: name, date of birth, contact details) will remain confidential and be kept linked to your study code in a separate, securely stored file accessible to the Investigators only. All information collected in the research project will be re-identifiable by the Investigators only and will be stored securely in locked cupboards (hard copies) and on password-protected computers in The ENT Centre, which is out of bounds for unauthorized staff or public. Your information will be kept for up to 15 years but will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Your information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities of the TGA or as required by law. By signing the Consent Form, you authorize release of, or access to, this confidential information to the relevant study personnel and relevant authorities as noted above.

 **FURTHER INFORMATION**

When you have read this information, a member of the research team will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact The ENT Centre on (02) 9476 1919. This information sheet is for you to keep.

This study has been approved by the Human Research Ethics Committee (HREC) - CRGH of the Sydney Local Health District (SLHD). If you have any concerns or complaints about the conduct of the research study, you may contact the Executive Officer of the Ethics Committee, on (02) 9767 5622 and quote study number 2020/ETH02712.

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# PARTICIPANT CONSENT FORM

I, .………………………………………………………………..…….……………………………..[name]

of…………………………………………………………………………………………………..[address]

have read and understood the Information for Participants for the above named research study and have discussed the study with………………………………………………………………………………………….
 [name of investigator]

* I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort, or potential side effect and of their implications as far as they are currently known by the researchers.
* I understand that, during the course of this study, my study records and medical records may be accessed by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.
* I understand that Chitodex with topical triamcinolone is not approved for use in Australia by the Therapeutic Goods Administration (TGA) and are not listed on the Australian register of Therapeutic Goods (ARTG). The researchers will submit a Clinical Trial Notification (CTN) to the TGA, which allows them to use Chitodex with triamcinolone in Australia for medical research purposes based on assessment and approval by an appropriately constituted Human Research Ethics Committee.
* I freely choose to participate in this study and understand that I can withdraw at any time.
* I hereby agree to participate in this research study.
* I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of my research data for up to 15 years at The ENT Centre and this will be maintained by the Coordinating Principal Investigator.

**Name (Please Print):** .

**Signature:** **Date:**

**Name of Person who conducted informed consent discussion (Please Print):**

……………………………………………………………………………………………………………….

**Signature of Person who conducted informed consent discussion:**

**Signature:** **Date:**