

**Princess Alexandra Hospital**

**Metro South Health**

**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

**Princess Alexandra Hospital**

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| **Title** | The in vivo performance of mucoadhesive, thermoresponsive soluble gels in healthy, adult nasal mucosa |
| **Short Title** | The in vivo performance of mucoadhesive, thermoresponsive soluble gels in healthy, adult nasal mucosa |
| **Principal Investigators** | Professor Ben PanizzaDr Angelica LynchAssociate Professor Peter CabotAssociate Professor Ben WallworkDr Harendra Parekh |
| **Location** | Princess Alexandra Hospital |

**Part 1 What does my participation involve?**

**1 Introduction**

You are being invited to participate in a research trial because you are an employee of Princess Alexandra Hospital. The aim of this research trial is to determine the length of time a soluble gel stays inside the nose and to determine whether the addition of a corticosteroid medicine affects this time.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to have the tests and treatments that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Chronic rhinosinusitis (CRS) is a common condition in which the cavities around nasal passages (sinuses) become inflamed and swollen for at least 12 weeks, despite treatment attempts. This then causes mucous build up.

According to the Australian National Health Survey, in 2007-2008, 9.2% of the Australian population reported to suffer from this condition. Symptoms include difficulty breathing through the nose, the area around the eyes and face may feel swollen and the patient may have facial pain or tenderness. Patients also frequently suffer from depression, poor sleep and fatigue leading to significant direct and indirect costs to the health system. Even though this condition is common in the community, there is an ongoing search for an efficient and practical method to deliver ongoing treatment that decreases the financial and physical burdens of CRS.

The most recent accepted standard treatment of CRS include nasal saline irrigation (washing the nasal passages with a mild salt water solution) and intranasal corticosteroid sprays/drops (applying medicine directly into the nose through drops or spray). Corticosteroids are medicines that assist in treating inflammation in the body. Current practice of adding a corticosteroid to the saline wash solution means the medication does not stay in the nose for very long and this then requires daily treatment.

Applying the corticosteroid directly to the inside of the nose (nasal mucosa) offers the benefits of treating CRS directly with high local concentrations without the systemic (whole body) side effects. There has been recent interest in the use of soluble gels, that gradually dissolve, which are applied directly to the inside of the nose to deliver these medicines. These soluble gels slowly release the medication into the surrounding tissue.

These gels have the potential to change the way medications are delivered to the nasal mucosa and thus the treatment of CRS.

The aims of this trial is to ascertain:

1. how long the soluble gel takes to dissolve once applied to the nasal mucosa
2. if the addition of a corticosteroid medication to the soluble gel affects the time it takes to dissolve.

This research has been initiated and conducted by the study doctors, Dr Angelica Lynch, Associate Professor Peter Cabot, Associate Professor Ben Wallwork, Professor Ben Panizza and Dr Harendra Parekh

**3 What does participation in this research involve?**

You will be asked to read this consent form carefully to determine if you would like to participate in this research project. Once you have consented to participating in this research project, you will be randomly assigned into one of two groups. This is called a randomised controlled trial. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. In this trial we will compare a medicated soluble nasal gel (sol-gel) in either gel or liquid form. The medication in the sol-gel is a corticosteroid, dexamethasone.

This trial has two stages: stage 1 and stage 2.

Stage 1

The first three participants in this study will have the medicated sol-gel administered to one of their nasal cavities. The sol-gel will be applied in liquid form.

Stage 2

In stage 2, the remaining participants will have the sol-gel administered in either liquid or gel form, randomly assigned.

**For all participants:**

In this trial we will administer the medicated sol-gel to one of your nasal cavities. This location will be randomly assigned. The sol-gels (either liquid or gel form) will have a water soluble blue dye added to them so the study doctors can see them easier.

You will not be told which type of sol-gel (liquid or gel) has been applied to your nasal cavity. This means the trial is blinded. Your study doctor will know and, if necessary, your study doctor will inform you in the case of a medical event or emergency.

You will be asked to avoid rinsing your nose with water and avoid forceful blowing of your nose during the study period.

Your study doctors will need to look inside your nasal cavity so they can tell how long the sol-gel stays there. To do this they will need to place a camera attached to a thin tube into your nasal cavities. This can cause some discomfort, hence, prior to camera insertion you will receive two sprays of a mild numbing medicine (Co-phenylcaine) into each nasal cavity whilst you are lying flat on a bed. The camera will then be inserted into your nasal cavity and photos taken.

**Stage 1 Participants only:**

The study doctors will take photos of your nasal cavity immediately after the sol-gel application.

After 5 minutes, your study doctor will wash out your nasal cavity with 200ml of sterile saline water at room temperature. They will then re-insert the camera to see if all the gel has been removed. If not, they will repeat the wash out until no gel is left.

**Stage 2 Participants only:**

The study doctors will take photos of the sol-gel inside your nasal cavities immediately following the sol-gels application and then at 2-4 hours and 6-8 hours after the sol-gel was initially applied (Day 1). The study doctors will take photos of the gel in your nasal cavities on the next day (Day 2) and then every three days after that (Day 5, Day 8) and then again on Day 12.

Each time your study doctors take photos of the sol-gel inside your nasal cavities they will assess how much is still there and to see if the sol-gel is causing any discomfort. Once the sol-gel is completely dissolved (no longer visible on the camera) you will be asked to complete a short questionnaire.

If your study doctor can still see then sol-gel on Day 12, your nasal cavities will be washed gently with a gentle salt water solution (sterile saline) at room temperature to remove the remaining sol-gel. The total volume of the saline wash will be 200ml (the same size as a small glass of water). You will be asked to complete a short questionnaire after once the nasal sol-gel is no longer visible.

The questionnaire will ask about nasal symptoms associated with the sol-gel, including blocked nose or trouble breathing through the nose, irritation, burning, runny nose, smell and taste.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, required as part of the research project will be provided to you free of charge.

**4 What do I have to do?**

You will need to meet the eligibility criteria to participate in this trial. You must be an employee of the Princess Alexandra Hospital and you must fulfil all of the eligibility criteria below:

Inclusion criteria

i. Employee of the Princess Alexandra Hospital

ii. Aged between 18-50

iii. Currently fit and healthy

iv. Available

Exclusion criteria

i. Sinonasal disease requiring intranasal or systemic medications

ii. Require more than one tissue per day to blow the nose

iii. Daily use of any steroid medication

iv. Allergies to any of the medications being used: dexamethasone, mometasone, lignocaine or phenylephrine

**5 Other relevant information about the research project**

This trial will be conducted at Princess Alexander Hospital. It is anticipated that 8 people will participate.

**6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the Princess Alexandra Hospital.

**7 What are the possible benefits of taking part?**

There will be no clear benefit to you from your participation in this research. Future benefits to patients may include an improvement to the treatment of CRS.

**8 What are the possible risks and disadvantages of taking part?**

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

It is unlikely you will experience any side effects from medications in this study. However, there is a small chance you may experience one or some of the following side effects as listed below:

**Co-Phenylcaine:**

The two nasal sprays used in this trial will numb your nose and throat. This may affect your ability to swallow until the effects of the drug have worn off. You are advised to avoid food and drink during the 4 hours following administration of each nasal spray. You are advised to avoid hot food and drink for 4 hours following administration of each nasal spray; because you may not be able to judge how hot food is due to the numbing effect of the spray. Numbness to the nose and throat should resolve within 2 hours. Other side effects may include:

1. Hives, itching, rash or visual sensitivity to light.

2. Increased heart rate or abnormal heart rhythm.

3. Raised blood pressure.

4. Tremor, irritability, nervousness or headache.

5. Chest tightness, shortness of breath.

**Dexamethasone**

Dexamethasone will be administered at very low doses (0.1% w/w). The most common side effect of this medication at this dose is irritation in the nasal passage and a mild headache.

Should you experience any of these symptoms, please let your study doctors know.

**9 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. You do not have to give any reasons for your decision to withdraw. If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information and data from you, although personal information and data already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

**10 Could this research project be stopped unexpectedly?**

This research project is not expected to be stopped unexpectedly. However, in the event that there are unacceptable side effects of the study drug or gel, the trial will be stopped.

**11 What happens when the research project ends?**

This research project will be registered on the Australian Government Clinical Trials website at <https://clinicaltrials.gov/> and updates on the trial outcomes will be available on this website for the public to read on completion of data analysis.

 **Part 2 How is the research project being conducted?**

**12 What will happen to information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. For the purpose of this research project, we will collect your name and your place/area of work. This will allow us to follow you up to 12 Days after application of the nasal gel. It will also allow us to collect any information from you regarding side effects. This information, as well as your signed consent form will be kept in a locked cabinet in a locked room. Only the study Investigators will have access to your consent forms.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

For the purpose of this trial, you will be allocated a unique study number. This number will be used when information about you is entered into a database. No personal information about you will be published.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

**13 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with 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.

**14 Who is organising and funding the research?**

This research project is being conducted by the study investigators. There is no funding for this research. The support of the investigators is in kind.

If knowledge acquired through this research leads to discoveries that are of commercial value to the Princess Alexandra Hospital, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**15 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by Metro South Human Research Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**16 Further information and who to contact**

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal investigator, Dr Angelica Lynch on 0438 135 895, or any of the following people:

 **Clinical contact person**

|  |  |
| --- | --- |
| Name | *Associate Professor Ben Wallwork* |
| Position | *Head and Neck Surgeon* |
| Telephone | *(07) 3176 2111* |
| Email | *ben@greenslopesent.com.au* |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | *Patient Liaison Officer* |
| Hospital | *Princess Alexandra Hospital* |
| Telephone | *(07) 3176 5598* |
| Email | *PAH\_PLO@health.qld.gov.au* |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | *Metro South HREC* |
| HREC Executive Officer | *Ethics Coordinator* |
| Telephone | *(07) 3443 8049* |
| Email | *EthicsResearch.PAH@health.qld.gov.au* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Consent Form -** *Adult providing own consent*

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| **Title** | The in vivo performance of mucoadhesive, thermoresponsive soluble gels in healthy, adult nasal mucosa  |
| **Short Title** | The in vivo performance of mucoadhesive, thermoresponsive soluble gels in healthy, adult nasal mucosa |
| **Principal Investigators** | Professor Ben PanizzaDr Angelica LynchAssociate Professor Peter CabotAssociate Professor Ben WallworkDr Harendra Parekh |
| **Location**  | Princess Alexandra Hospital |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

**Declaration by Study Doctor**†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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| --- |
|  |
|  | Name of Study Doctor (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.