**PARTICIPANT INFORMATION SHEET AND CONSENT FORM**

**Title:** Effect of Irrigation bottle size on nasal saline irrigation following sinus surgery.

**Chief Investigator**

Professor A. Simon Carney

Department of Otolaryngology – Head & Neck Surgery

Flinders University

Tel: (08) 8277 2088

**Practice Manager**

Tracey O’ Neil

Adelaide Specialist Group

tracey@adelaidesg.com.au

Tel: (08) 8277 0288

**Co-Investigator**

Do Hee Kim (Hailey)

College of Medicine and Public Health

Flinders University

Timothy Lin

College of Medicine and Public Health

Flinders University

**Description of the study**

This project will investigate the effect of a change in the volume of irrigation bottles on the effectiveness of nasal irrigation for sinus surgery patients. This project is supported by Flinders University, College of Medicine and Public Health.

**Purpose of the study**

This project aims to determine whether 200ml or 400ml irrigation bottles change post-surgical outcomes in patients who have undergone sinus surgery. Nasal irrigation is an essential procedure for post-surgical care. However, there is currently no research comparing the volume of irrigation bottles used. This study aims to fill this gap in literature. The results of this study will provide us with the knowledge necessary to guide future clinical care in order to provide the best patient outcome.

**Benefits of the study**

The sharing of your experiences will help to understand whether perhaps the changeing the volume of the irrigation bottle provides better quality of life and outcomes and hence allowing better informed clinical decisions in post-surgery care for patients.

**Participant involvement and potential risks**

Initial Steps

If you wish to take part in this study, Professor Simon Carney will speak with you and ask you a few questions to make sure that you meet the criteria needed for being a participant in this study. If you have a history of frequent or active nosebleed, high risk of choking on your food and significant history of craniofacial surgery/abnormalities, you may be ineligible for the study. You must also be able to attend the clinic every 2 weeks. There will be additional information sheets provided to you which may answer any queries you have. You are welcome to discuss your decision with your family or have some time to think prior to making your decision before your next consult.Professor Carney will introduce the study but it is important you read the information sheet in your own time before making a final decision. It is important that you understand you clinical care will not be affected in anyway if you choose not to participate.

Research procedure and commitment required

If you’re happy and you sign the consent form, then you will be part of our study as a participant. You will then be randomised to one of two groups. You have an equal (50:50) chance of being in either group. You will either be given a 200 ml or 400 ml nasal irrigation bottle for use, depending on your assigned group. During the 2 weeks, you will be given sachets of normal saline solution (FLO Sinus Care) together with the bottle. It is important that you use the sachet each time you rinse as this is part of the management. The sachets and bottle will be provided free of charge.

You will be given written instructions and a link to a YouTube video demonstrating how to irrigate your nose. Many people already know how to do this but please read the instructions provided under the FLO SINUS KIT information sheet in full just in case you might be doing something different by accident. There is additional information provided about nasal irrigation in the Nasal Douching Fact Sheet as well.

Over the course of 2 months, you will be required to perform the irrigation procedure daily for 2 weeks. On every 14th day, you will need to return to our rooms. At each visit you will be asked to fill out a simple quality-of-life questionnaire (SNOT-22 questionnaire). This questionnaire assesses 22 symptoms which comprises of 5 domains: nasal, ear/facial, sleep, function, and emotion. Next, Professor Simon Carney will observe your sinuses and have them scored, before conducting tympanometry to test for any signs of eustachian tube dysfunction (ETD). Tympanometry involves putting a small probe into each ear which will push air into your ear. This will assess how well your eardrum moves, and if the irrigations have affected it in any way.

Type of study

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). In this study you have a 50:50 chance of receiving one of two saline solutions.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

Potential risks

Medical treatments often cause side effects. You may have none, some, or all 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 any side effects noted.

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 develop.

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.

**Possible side effects**

The risk of bleeding and pain are identical to those patients not participating in this trial. No modification to existing irrigation techniques is happening.

Minor irritation and nose dripping

Saline nasal irrigations are usually performed with no side effects whatsoever. You will taste some of the salty water in your throat but as it is in balance with your own body fluids, it won’t cause you any harm. If some of the saline wash goes into your sinuses, you may notice a small amount drip out of your nose a few minutes later.

Ear problems

In a small number of individuals, the wash can irritate the tube between the back of your nose and the ears. This can cause your ears to feel blocked or “pop” more regularly than usual. This is known as Eustachian Tube Dysfunction. You will be monitored for this at each visit, but if this occurs, please let your study doctor know and if it’s causing a quality of life issue, we will ask you to stop the irrigations.

**Withdrawal Rights**

You may decline to take part in this research study. If you decide to take part and later change your mind, you may, withdraw at any time without providing an explanation.

**Confidentiality and Privacy**

Only researchers listed on this form have access to the individual information provided by you. Privacy and confidentiality will be assured at all times. The research outcomes may be presented at conferences and be written up for publication as described in this information form. However, the privacy and confidentiality of individuals will be protected at all times. You will not be named, and your individual information will not be identifiable in any research products without your explicit consent.

No data, including identifiable, non-identifiable and de-identified datasets, will be shared or used in future research projects without your explicit consent.

**Data Storage**

The information collected will be stored securely on a password protected computer and/or Flinders University server throughout the study. Any identifiable data will be de-identified for data storage purposes unless indicated otherwise. All data will be securely transferred to and stored at Flinders University for 15 years, after publication of the results. Following the required data storage period, all data will be securely destroyed according to university protocols.

**What do I have to do?**

As a volunteer participating in this project there will be no alterations to your day-to-day routine (including but not limited to your lifestyle, diet, medication plan and blood donation choice).

Participating in this study requires four visits to the Southern ENT clinic at the Flinders Private Hospital. These visits will actually be part of your normal consultation plan. Over the 2-month period, you are required to perform this daily nasal irrigation procedure as explained prior to participating in this study.

**Recognition of Contribution / Time / Travel costs**

If you would like to participate, in recognition of your contribution and participation time, you will be provided with a $25 Coles voucher. This voucher will be provided to you face-to-face on completion of the trial. Your car parking will also be reimbursed up to $30 in total.

**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 routine treatment, your relationship with Professor Carney, other doctors treating you or your relationship with Flinders University.

**How will I receive feedback?**

On project completion, a short summary of the outcomes will be provided to all participants via email.

There will be a tick box at the end of this form for patients to be notified of the results of the trial if they wish.

**Ethics Committee Approval**

The project has been approved by Flinders University’s Human Research Ethics Committee (6224).

**Queries and Concerns**

Queries or concerns regarding the research can be directed to the research team. If you have any complaints or reservations about the ethical conduct of this study, you may contact the Flinders University’s Research Ethics and Compliance Office team either via telephone (08) 8201 2543 or by emailing the Office via human.researchethics@flinders.edu.au.

Thank you for taking the time to read this information sheet which is yours to keep.

If you accept our invitation to be involved, please sign the enclosed Consent Form.

**CONSENT FORM**

**Title:** Effect of Irrigation bottle size on nasal saline irrigation following sinus surgery.

(6224).

**Consent Statement**

[ ]  I have read and understood the information about the research, and I understand I am being asked to provide informed consent to participate in this research study. I understand that I can contact the research team if I have further questions about this research study.

[ ]  I am not aware of any condition that would prevent my participation, and I agree to participate in this project.

[ ]  I understand that I am free to withdraw at any time during the study.

[ ]  I understand that I can contact Flinders University’s Research Ethics and Compliance Office if I have any complaints or reservations about the ethical conduct of this study.

[ ]  I understand that my involvement is confidential, and that the information collected may be published. I understand that I will not be identified in any research products.

[ ]  I understand that the information collected may be published.

I further consent to:

[ ]  attending every 2 weeks for 2 months to assess the state of my ears about eustachian tube dysfunction and my sinuses to confirm

[ ]  completing questionnaires

[ ]  sharing my de-identified data with other researchers

[ ]  my data and information being used in this project for an extended period of time (no more than 15 years after publication of the data)

[ ]  being notified of the result of the trial on completion

 Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signed:**

**Name:**

**Date:**