Two-Step versus One-Step Sub-Retinal Injection

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

INTRODUCTION

You are invited to participate in this study because you have bleeding under the central part of the retina, the macula, and have been advised to undergo surgery.

This study is being conducted by Associate Professor Matthew Simunovic (Visiting Medical Officer, Vitreoretinal Unit, Sydney Eye Hospital).

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information. You might want to speak to a relative, close friend or your GP about taking part. If there is anything you are unsure of, please do not hesitate to ask us.

1. What is the purpose of this study?

The purpose of this study is to investigate the best way of delivering "clot-busting" medication under the retina - in particular, under the central portion, the macula. There are two ways of doing this, either directly injecting the medication ("one-step injection") or by firstly injecting a watery solution to raise a blister and then injecting the medication into this blister ("two-step injection").

2. Why have I been invited to participate in this study?

You have been invited to participate in this study because you require eye surgery (vitrectomy) involving the use of a clot-busting medication.

3. What does this study involve?

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

You will be undergoing vitrectomy surgery for bleeding under the macula. A vitrectomy is a micro-keyhole surgery in which the gel inside the eye is removed using small instruments. After vitrectomy is completed, a small amount of clot-busting medication is injected under the macula using a fine needle.

Study Procedure:

The study procedure involves comparing two different ways of injecting this medication – either directly under the macula or as a two-step process in which the retina is raised by injecting a watery solution (balanced salt solution). Both methods are used in clinical practice, but we would like to find out which method is best at delivering the clot-busting medication.

We will use a yellow dye (fluorescein) to follow the flow of the medication under your macula. (You will notice bright yellow colouring of your urine up to 24-36 hours after the surgery). **Please inform the study investigator if you have a known allergy to fluorescein or contrast dye.**

At the end of your surgery, a small sample of this yellow dye fluid will be kept (instead of being thrown away, as is normally the case). This fluid will be examined in our laboratory to determine how much medication has escaped from under your retina during the surgery. After analysis, your sample will be destroyed.

Your surgery will also be video-recorded so that we can observe the flow of the medication and yellow dye at the time of injecting the clot-busting medication. You will not be able to be identified in this video and all footage will be destroyed at the completion of the study.

You will have an equal chance to be randomly allocated into one of the two methods. The study group you will be assigned to will be determined by chance, similar to a flip of a coin. You will not be able to choose which study group you want to be in.

If it becomes apparent that one of the two groups does especially well, or especially poorly, or if it is proved that another treatment will provide superior outcomes during the conduct of this trial, this study will be terminated. We do not expect one group to fare significantly better than the other. If you decide to participate, we will continue your post-surgery follow-up according to hospital standard of care (usually for up to 12 months), regardless of the study outcomes.

You will not be asked to come in for additional study visits following your surgery. Information for the study will be collected by the investigator/s at your regular post-operation appointments, as advised by your treating doctor. At these visits, you will be asked whether you have had any side effects or discomfort from the procedure, and to list all medications you are taking (including start and stop dates).

Standard Procedures:

The following is a description of the eye examinations and tests that will be performed prior to and after your surgery. These tests are a part of standard care, you will have the same procedures performed whether you decide to participate in this study or not. Please ask your study team members questions about any words or procedures that you are unfamiliar with. All procedures will be done on both eyes.

Visual Acuity
The visual acuity examiner will measure your vision with your usual prescription, and with a pinhole. This is standard of care at each visit and will take 5 minutes.

Optical Coherence Tomography (OCT)
The OCT is used to examine the retinal thickness of your eyes by taking pictures of the retina. The OCT will be repeated to determine whether retinal thickening is getting worse, better or remains the same. This test can take up to 5 minutes

Intraocular Pressure (IOP) & Eye Examination
You will be given a complete eye examination, similar to those done for your regular eye check. The pressure in each eye will be measured and after dilating your pupils with drops, the lens and back of your eye will be examined. This can take up to 15 minutes.

Note: You will also have your pupils dilated at each visit (as per usual clinical care) and we recommend you arrange to have someone drive you to and from the visits, or alternatively take a taxi or public transport.

4. What are the risks associated with this procedure?

The risks for vitrectomy surgery are the same as those for patients not taking part in the trial:

Very Common (occurring in at least 1 in 10 participants treated):
- Bleeding of the thin membrane covering the white of the eye and inner lid,
- Temporary increase in the pressure in the eye
- Eye pain

Common (occurring in at least 1 in 100 to 1 in 10 participants treated):
- Eye irritation
- Swelling of the thin membrane covering the white of the eye and inner lid
- Feeling that there is something in the eye

Uncommon (occurring in at least 1 in 1000 to 1 in 100 participants treated):
- A serious eye infection called endophthalmitis

The only additional risk in this study is that a yellow colouring (fluorescein sodium), will be added to the clot-busting medication to track the flow of the medication in the eye. Fluorescein sodium has been used for studying eye and retinal disease for more than fifty years and is agreed to be a safe medication. We will be using fluorescein at a lower concentration, which has been shown to have no known detrimental effects. **If you know yourself to be allergic to fluorescein, please notify the study doctor immediately.**

5. Will I benefit from this study?

The testing will not provide you with any direct benefit. However, it may provide valuable information to improve the management of patients requiring sub-retinal injections in the future.

6. What happens if I don't want to take part in the study?

Participation in this study is voluntary. It is completely up to you whether you participate. If you decide not to participate, this will not affect the treatment you receive now or in the future and will not affect the relationship with the health professionals caring for you.

You may withdraw from this study any stage.

7. How will my confidentiality be protected?

Although your sample will be linked to information identifying you, all aspects of this study will be kept confidential and only those conducting and monitoring the study will have access to your results. The link between your personal information and your sample will be removed before your sample is analysed in the laboratory.

Once the data pertaining to your participation in the study has been de-identified for study statistical analyses, it will not be possible to exclude your results, should you decide to withdraw from the study.

Any identifiable information collected about you in connection with this study will remain confidential and will be disclosed only with our permission, or except as required by law. Results will be held securely at Save Sight Institution, Sydney Eye Hospital.

We plan to discuss and/or publish the findings. In any publication, information will be provided in such a way that you cannot be identified.

8. What will happen to my sample after it has been tested?

Your sample will only be used for the purpose of this study and will be destroyed after laboratory analysis has been completed.

9. Will I be able to withdraw my sample if I want to?

It is not appropriate to return your sample to you. However, you may contact your study doctor at any time and request that your sample be destroyed.

10. How is this study being paid for?

The study is funded by the US-based charity, the Foundation Fighting Blindness, and is under the direction of A/Prof Matthew Simunovic and the research staff at Save Sight Institute, Sydney Eye Hospital.

11.What should I do if I want to discuss this study further before I decide?

When you have read this information, we will discuss it with you and answer any queries you may have. If you would like to know more at any stage, please do not hesitate to contact us as per the details below.

12.Who should I contact if I have concerns about the conduct of this study?

This study has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research Support Office which is nominated to receive complaints from research participants.

You should contact them on 02 9382 3587, or email and quote HREC project number: 17/092.

13. What happens if I suffer injury or complications as a result of the study?

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

Contact Details

You are encouraged to ask the study doctor/study coordinator any questions about this study or this information sheet. If you have any questions or experience any research-related injuries during the study, you should contact the following:

Study Doctor:
A/Prof. Matthew Simunovic Tel: 02 9382 7111
Mob: 0424 588 644

Study Coordinator:
Stella Xu Tel: 02 9382 7309

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

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PARTICIPANT CONSENT FORM

I ……..*[name]* of

……*[address]*
agree to participate as a subject in the study described in the Participant Information Sheet set out above.

- I acknowledge that I have read the Participant Information Sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.
- Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
- I understand that I can withdraw from the study at any time without prejudice to my relationship to Sydney Eye Hospital and Save Sight Institute.
- I agree that the research data gathered from the results of the study may be published, provided that I cannot be identified.
- I understand that if I have any questions relating to my participation in this research, I may contact A/Prof Matthew Simunovic on telephone (02) 9382 7111, who will be happy to answer them.
- I acknowledge receipt of a copy of this Consent Form and the Participation Information Sheet.

Complaints may be directed to the Research Support Office, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031 Australia. Tel: (02) 9382 3587 Fax: (02) 9382 3587 Email SESLHD-RSO@health.nsw.gov.au

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____
Signature of witness	**Please PRINT name**	**Date**
_____	_____	_____
Signature of investigator	**Please PRINT name**	**Date**
_____	_____	_____

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WITHDRAWAL OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with Sydney Eye Hospital or my medical attendants.

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____

(To be signed and dated by participant)

The section for Revocation of Consent should be forwarded to:

A/Prof Matthew Simunovic
Sydney Eye Hospital
8 Macquarie Street
Sydney NSW 2000