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SA Health

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Patient information sheet

The Effect of Near-Infrared Laser on Contrast Sensitivity in Human glaucoma (NIRG TRIAL)

INTRODUCTION

You are being asked to join a clinical research study, as you have been diagnosed with glaucoma.

Glaucoma: is a disease in which the optic nerve is damaged, leading to progressive, irreversible loss of vision. It is often, but not always, associated with increased pressure of the fluid in the eye.
The study is being conducted by Professor Casson at The Royal Adelaide Hospital.

This information sheet may contain words that you do not understand. Before you decide whether or not to participate, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your doctor if you wish. Please ask your study doctor if there is anything you do not understand or if you would like more information.

WHAT IS THE PURPOSE OF THE STUDY?

We are trying to assess the effectiveness of a new type of low-energy laser. This laser is currently being studied in diabetic eye disease and we believe that it may be effective in glaucoma. The laser improves the energy supply to sick nerve cells at the back of the eye, especially those affected by glaucoma. We are hoping that this laser may actually improve vision in glaucoma. It is a very safe laser and if successful is likely to be used in conjunction with eye pressure lowering treatment.

The purpose of this study is to establish a proof of a principle known as neuroprotection.

Neuroprotection: refers to the ability to directly promote survival of the optic nerve.

The optic nerve is the nerve that transmits visual information from the retina to the brain.

Contrast sensitivity: is the ability to differentiate between light and dark (contrast).

This study is to assess whether low doses of Near Infrared (NIR) laser light are beneficial in improving contrast sensitivity in glaucoma patients.

Lasers are routinely used and are approved in Australia for treating a variety of eye diseases these lasers are called Thermal Lasers and are usually green in colour. They are applied to the retina through a special type of microscope and many laser spots are individually placed over the affected area. In all cases, these lasers work by burning small areas of the retina in order to trigger the required healing response that, with time, decreases the amount and extent of the swelling. We are trying to assess the effectiveness of a new type of NIR laser that is about 100 times lower in power density than a Thermal Laser. The NIR laser causes no burn; however, it appears to stimulate a healing response to injured cells and reduces edema and enhances cellular function.

UNDERSTANDING THE STUDY METHOD

This study method is described as: a **prospective, randomized, double-masked pilot study**.

If you decide to take part in the study and meet all the requirements, you will be chosen randomly by chance (similar to tossing a coin) to be randomized into one of the two groups. You will have a 1 in 2 chance (50%) of getting one of the following procedures: the active laser or a sham laser (control). You will have the same treatment throughout the study. You will not know which group you're in.

The study has the 2 treatment arms (groups) an active arm group and a control arm group.

The **active arm** group gets treated with the **laser**

The **control arm** group gets treated with a **sham laser**. In sham treatments, the doctor goes through the motions without actually performing the treatment.

Sham treatments are methods used in medical trials to help researchers determine the effectiveness of a drug or treatment.

WHO WILL TAKE PART IN THIS STUDY?

Approximately 16 participants aged 18 years and above.

WHAT WILL HAPPEN TO ME DURING THE STUDY?

If you decide to take part in the study, you will be asked to sign and date the Participant Consent Form. A copy will be given to you to keep.

This study may be suitable for you if you have macular glaucoma in one or both of your eyes; if both eyes are eligible both would be treated

The study treatment techniques are described in more detail below.

- The study will last for 2 weeks with up to 5 visits.
- The first visit, baseline review will be up to 1.5 hours.
- The 3 treatment visits would be up to 30 mins and the final visit up to 1.5 hours.
- You will have a total of 3 laser treatments, ideally on a Monday, Wednesday and Friday.

THE FIRST VISIT (SCREENING)

Your first visit for this study will be a screening visit to check if the study is suitable for you.

Please see the tests and their explanations in the table following.

PROCEDURE	WILL BE DONE LIKE THIS:	VISIT
Medical/medication and Ophthalmic history	You will be asked about your general medical history, including our vision and eye health. You will also be asked about your medications, prescriptions and over the counter medications.	screening
Blood pressure	Using the blood pressure assessing equipment your blood pressure will be taken.	every visit
Auto refraction	A non-invasive test of your eyes using equipment and a computer program to test and measure your vision. It calculates weather you could see more clearly with help of corrective lenses. It determines the strength of the lens you may need.	screening and final
Vision test - acuity	You will be asked to read letter from a 4 metre chart. You may be asked to wear a metal eyeglass frame for this test. The assessor may place different lenses in the frame to find which ones best adjusts your vision.	every visit
Contrast Sensitivity Test	The test simply involved looking at circles from a purpose built chart. The circles of are different shades of grey. The test is completely non-invasive.	screening and final
Automated Visual Field Test	A visual field test measure how much 'side' vision you have. It is a straightforward test, painless and does not involve eye drops. Essentially lights are flashed on and off and you have to press a button whenever you see the light. You head and eyes are kept still whilst resting your chin on a chin rest.	Screening and final
Slit lamp of front of eye	To examine the front of your eyes with a special magnifying microscope (slit lamp), the study Doctor will review the front aspects of your eyes.	screening and final
Eye Pressure Measurements	The measurement is quick and pain free using a small piece of equipment called an Eyecare tonometer. No anaesthetic is needed. This is a standard procedure in the eye clinic.	every
Optical Coherence Threshold (OCT)	Ocular Coherence Tomography or OCT. This is a non-invasive, non-contact imaging technique to check the thickness of different aspects of eyes(both eyes).	
Adverse Events	You will be asked if you have experienced any adverse events	every visit after screening

In addition, the following procedures will be done:

- Medication and Health Review. You will be asked some questions about your current health, your medical and eye related history (including history of injuries, illnesses, and surgery). Your study doctor will also review any medications and vitamins/dietary supplements you may be taking (both prescription and over-the-counter). Please bring a list of these.

If the results of the above tests and procedures show that the study is suitable for you, you will receive your first NIR laser treatment on the Monday of the week following your screening visit.

WHAT IS THE ACTUAL TREATMENT PROCEDURE?

The treatment procedure will be the same for both of the groups, the active group and the sham group.

The treatment technique is very straightforward. Each treatment will consist of a 90 second exposure of the eye to the NIR laser. You will be seated in a chair and you will receive a dilating eye drop as well as a drop of anaesthetic into the eye to be treated to make the treatment more comfortable. A small contact lens will then be placed on your eye and your head will be settled into a headrest so that the doctor can examine and treat your eye with a special microscope. The microscope is used to view your macular and to shine the laser into your eye for the exposure period. We do not believe that this will be painful. Only the outer macula will be treated in this study, so if there are unexpected side effects of the laser they will not affect your central vision.

SUBSEQUENT TREATMENT VISITS

Following your first visit you will need to report to the clinic for treatment an additional 3 times.

FINAL VISIT

The final visit will be a repeat of the examinations performed at your screening visit.

Blood pressure, Vision testing, Contrast Sensitivity testing, Humphrey Field Test, Eye pressure measurement, Optical Coherence tomography and review of the front of your eye.

If you leave the study early, we will ask that you return for a final visit to have the assessments as set out in the table attached.

ARE THERE ANY RISKS?

There may be risks to you if you participate in this study. All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions,

you might develop medical complications from participating in this study. The known risks of this study are:

RISKS OF NIR LASER TREATMENT

The side effects of this treatment are unknown. There have been no side effects reported in previous studies involving around 20 patients treated with the NIR light. One person who is a long time migraine sufferer had a sensation of being more susceptible to having a migraine after one treatment session however no migraine developed. This was recorded as a minor adverse event.

During the follow up visits, you will be checked for potential side effects and the results discussed with you. Any new problems you notice during the study, which may affect your condition or your decision to stay in this study, should be discussed with your study doctor.

What should I be aware of and worried about?

It is extremely important that you are aware of any symptoms that might indicate one of the following complications, and that you report new symptoms to your eye doctor. Any or all of these side effects may cause loss of vision.

The symptoms to be aware of include:

- Eye pain or increased discomfort
- Worsening eye redness
- Blurred or decreased vision
- Increased sensitivity to light

OTHER POSSIBLE RISKS OR DISCOMFORTS

Local anaesthesia (numbing) involves placing a topical eye drop on your eye which might cause slight temporary stinging or discomfort (but no pain) which resolves over a few minutes.

During slit lamp microscope examination of the eye, as well as treatment with the NIR Laser, a special contact lens is used to aid observation of the retina. A few drops of viscous gel are used to aid placement of the lens on the eye. Some patients may experience mild irritation from this gel but this should disappear within a few hours.

Use of drops to dilate the pupil is standard for any eye examination. The drops may briefly sting the eye, and pupil dilation may cause sensitivity to light and blurring of vision for several hours. It is recommended that you do not drive while your eyes are dilated.

You may feel temporary discomfort during the eye examinations and photographs due to the bright lights. You may feel mild to moderate momentary discomfort when the doctor puts pressure on your eye (through the eyelid) to examine the back of your eye.

Optical coherence tomography (or OCT) measures the thickness of the macula using a very low intensity laser. There is minimal discomfort due to the light, and no other risks are associated with this test.

Because NIR Laser therapy is an experimental treatment, not all risks and side effects are known.

If you have any questions or concerns regarding any of these risks, please consult with your doctor.

PREGNANCY

The risks to an unborn baby or a breastfeeding child from NIR Laser treatment are not known. Therefore, women of child-bearing potential will be required to have a pregnancy test prior to entry into this study. The results of the test must be negative for you to receive the treatment procedure. You will be required to use an effective method of birth control throughout the study. If you are pregnant, you cannot enrol in the study. If at any time during the study, or within 30 days of completion of the study, you suspect that you have become pregnant, you must notify the study doctors immediately.

POTENTIAL BENEFITS

It is possible that NIR Laser treatment may assist but there is no guarantee that you will receive any direct medical benefits from this study. Your condition might not improve or may worsen while you are in this study, but we are hopeful that the information learnt from this study will benefit other people with glaucoma in the future.

PARTICIPANT RESPONSIBILITIES

You should return promptly for all study visits, and report any changes in your medications (over-the-counter and prescription) and in how you feel to your study doctor Professor Casson.

CONFIDENTIALITY

This study will involve the collection and processing of personal data about you by your doctor including sensitive data regarding your health and other personal details. All personal data that is removed from the study site will be marked with a patient number (coded) that will be assigned to you at the beginning of the study. The coded data will be used for purposes related to this study and any other studies arising out of this study such as research and development, statistical analysis, the licensing and registration of pharmaceutical products and/or medical devices, the provision of healthcare, market research and other related purposes. By agreeing to participate in this study, you are giving your permission for the Investigators to process your coded personal and sensitive data for purposes related to this study.

If you are admitted to another hospital during the course of, or arising out of, your participation in the study, you are asked to give your permission for the release of

any relevant records from that hospital. This would include records relating to a stay in the hospital and may include such information as test results, medications you were given during your stay and the reason why you were hospitalised.

A report of the results of this study may be published or sent to the appropriate health authorities in any country in which the product may ultimately be marketed but your name will not be disclosed in these documents. Appropriate precautions will be taken to maintain confidentiality of medical records and personal information.

Auditors, the Ethics Committee and regulatory authorities will be granted direct access to your medical records for the verification of study procedures and data in accordance with Australian law. By signing and dating the Participant Consent Form, you will be authorising such access.

The investigators are committed to respecting the privacy of all patients taking part in this study and, to this end, uphold the provisions and principles of the Australian Privacy Act. In particular, they will respect your rights in relation to your data including your right to correct your personal data and your right to have access to your personal data in the Investigator's possession.

The Therapeutic Goods Administration requires your study records to be retained for 15 years after the completion of the study. After this period, the records will be shredded, incinerated or securely recycled.

Your GP and/or relevant specialist will be informed of your participation in this study and by signing and dating the Participant Consent Form, you will also be giving permission for information regarding your medical history or your ongoing medical condition to be obtained from your GP and/or relevant specialist.

MEDICAL TREATMENT COMPENSATION

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. 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.

In addition, 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 sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). You do not give up any legal rights to compensation by participating in this study.

Financial Disclosure

Neither you nor your doctor will be paid for your involvement in the study.

WILL I BE REIMBURSED?

There will be no charge to you for the tests, examinations and medical care required as part of this study.

DO I HAVE A CHOICE?

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you.

NEW INFORMATION

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

WHAT WILL HAPPEN AT THE END OF THE STUDY?

This is a research study, and NIR Laser therapy is not registered for use in patients with glaucoma in Australia at the present time and may never be registered. If this treatment becomes registered, then it may not be subsidised by the Medicare Benefit Scheme PMBS) in Australia. The Investigators cannot commit at this stage to provide this treatment to you after the study is over.

ADVICE AND INFORMATION

If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the chairman, Research Ethics Committee, Royal Adelaide Hospital on **8222 4139**

When you have read this information, Professor Casson or their colleague 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 him/her (contact details listed below).

This information sheet is for you to keep.

CONTACT DETAILS

You are encouraged to ask the study doctors 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 Professor Robert Casson	Telephone Number: 08 8222 2729
Study Coordinator: Kylie Dansie	Telephone Number: 08 8222 2736
On call emergency Eye Doctor	Telephone Number: 08 8222 4000

The Effect of Near-Infrared Laser on Contrast Sensitivity in Human glaucoma (NIRG TRIAL)

PARTICIPANT CONSENT FORM

I,
.....
[name]

Of
.....*[address]*

have read or have had read to me and understood the Information for Participants on the above named research study

and have discussed the study with
.....

- 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 my participation in this study will allow the researchers and others, as described in the Information for Participants, to have access to my medical record held at this clinic and at other hospitals/clinics at which I seek treatment during the study, and I agree to this.
- I freely choose to participate in this study and understand that I can withdraw at any time.
- I also understand that the research study is strictly confidential.
- I hereby agree to participate in this research study.
- I have been given the opportunity to have a member of my family or another person present while the study is explained to me.
- I understand that I am free to withdraw from the study at any stage without prejudice to future treatment. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- I am 18 years of age or over.
- I consent to my treating Doctor/s being notified of my participation in this study and of any clinically relevant information noted by the study doctor in the conduct of the study.
- I understand the statement concerning payment to me for taking part in this study, which is contained in the information sheet

- I understand that I should not become pregnant during the course of this study, in the event of a pregnancy occurring, I agree to notify the investigator as soon as is practically possible.

- I declare that all my questions have been answered to my satisfaction.

Signature of participant **Please PRINT name**
Date

_____ _____

(To be signed and dated by participant)

Signature of witness **Please PRINT name**
Date

_____ _____

(To be signed and dated by witness)

Signature of investigator **Please PRINT name**
Date

_____ _____

(To be signed and dated by the person who conducted the informed consent discussion)