North West Anglia NHS Foundation Trust

PARTICIPANT INFORMATION SHEET

Study Title: **HALO**

A feasibility study: The efficacy and safety of **H**eat **A**pplied to closed eye**L**ids in enhancing the delivery of **O**cular hypotensive eye drops in the treatment of Primary Open Angle Glaucoma

You are being invited to take part in an NHS research study. Before you decide whether or not to take part it is important to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. One of our team will go through this information sheet with you and answer any questions you may have. Please ask us if there is anything that is not clear or if you would like more information at this time. Thank you for reading this.

This information sheet consists of two parts:
Part one tells you the purpose of this study and what will happen to you if you take part.
Part two gives you more detailed information about the conduct of the study.

If you would like any further information about this study then please contact the Ophthalmology research team:

Catherine Willshire (Research Optometrist/Principle Investigator) Tel: 01480 363880/363881
Email: Catherine.willshire@nhs.net

Mr Safdar Alam (Chief Investigator) Tel: 01480 416194 (ext - 6194)
Email: safdaralam@nhs.net

Support and confidential advice can also be found through your hospital's NHS Patient Advisory Liaison Service (PALS) Telephone Hinchingbrooke (HH): 01480 428964 or Peterborough City Hospital (PCH) Tel:01733 673405

Email for HH Hch-tr.pals@nhs.net and PCH: nwangliaft.pals@nhs.net

PART ONE

Why have I been invited?

You have been invited to take part in this study because you have been diagnosed previously with glaucoma or ocular hypertension and to reduce the pressure in your eyes, you are treated with eye drops that you apply in the morning under the care of the glaucoma specialists at the regional glaucoma center at North West Anglia NHS Foundation Trust (NWAFT- **Hinchingbrooke Hospital or Peterborough City Hospital**).

Aim of this study

To investigate whether applying gentle heat to closed eye lids of patients with Glaucoma or Ocular Hypertension in combination with pressure lowering drops can result in further decrease in eye pressures.

What is the purpose of the study?

Glaucoma is an eye disease which can lead to irreversible loss of vision caused by damage to the optic nerve at the back of the eye. It is often associated with raised fluid pressure in the eye and is treated mainly by drops that lower this pressure. However, only a small amount of the eye drop enters the eye because of overspill onto the eye lids and excess tear formation. This can mean that the eye drops may not have the maximum effect on lowering the eye pressure and result in the need to use additional eye drops or progress to surgery. In the Glaucoma clinic we try to keep to the simplest form of treatment to maintain eye health as this improves compliance, reduces side effects of the drops and the risks associated with surgery.

As a result of this study, we hope that eye doctors will be able to determine whether the use of goggles that provide a gentle heat to the eyelids when the eyes are open will improve the effectiveness of the Glaucoma eye drops. The warming goggles have been used for many years as a treatment to unblock the oil glands that are present on the upper and lower eyelids and have an excellent safety record.

Because we do not know whether the addition of heat will enhance the effectiveness of the eye drops, participants will be asked to attend the clinic for three visits where we will measure the eye pressures with and without the addition of eyelid warming.

Do I have to take part?
No, your participation in this is entirely voluntary and you are under no pressure to take part. It is up to you whether or not you decide to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

Who else will be taking part in the study?
We will recruit patients from glaucoma clinics at NWAFT – Hinchingbrooke and Peterborough City Hospital.

Have any studies like this been done before?

Many studies have looked into the safety of the warming goggles and have found them to be a safe and effective method of treating blocked oil glands on the eyelids. No one has used the eyelid warming in combination with pressure lowering eye drops to see whether the effectiveness of the treatment can be enhanced.

What will happen to me if I take part?

If you agree to take part, you will be asked to attend your chosen hospital for the following visits:

- Screening visit*:* to make sure that you are suitable to take part in the study. This visit will include completing a consent form, starting a diary about how you use your eye drops, a visual fields test (if this has not been completed within the last three months) and gathering some information about your health and eye history. This visit will take approximately 90 minutes.
- Visit one*:* measuring the eye pressures without eyelid warming. This visit will include completing two questionnaires one about your general health and one about how your eyes feel, we will examine your eyes using some bright lights and measure your vision. We will then ask you to put in your Glaucoma eye drops and start measuring your eye pressures. We need to check the eye pressures at five different time points during the day (8:30, 10:30, 12:30, 14:30 and 16:30). You do not need to stay in the eye clinic in between these time

points and you will be given an allowance for refreshments to use throughout the day. This visit will last approximately eight hours.

- Visit two: measuring the eye pressures with eyelid warming.
  This visit will include completing two questionnaires one about your general health and one about how your eyes feel. We will examine your eyes using some bright lights and measure your vision. We will then ask you to wear the warming goggles for 10 minutes (we will ask you to keep your eyes closed during this time) before putting in your Glaucoma eye drops and start measuring your eye pressures. We need to check the eye pressures at five different time points during the day (8:30, 10:30, 12:30, 14:30 and 16:30). You do not need to stay in the eye clinic in between these time points and you will be given an allowance for refreshments to use throughout the day. This visit will last approximately eight hours.

- Visit three: measuring the eye pressures with goggles but no warming.
  This visit will include completing two questionnaires one about your general health and one about how your eyes feel. We will examine your eyes using some bright lights and measure your vision. We will then ask you to wear the goggles for 10 minutes (with **no** heat – we will ask you to keep your eyes closed during this time) before putting in your Glaucoma eye drops and measuring your eye pressures. We need to check the eye pressures at five different time points during the day (8:30, 10:30, 12:30, 14:30 and 16:30). You do not need to stay in the eye clinic in between these time points and you will be given an allowance for refreshments to use throughout the day. This visit will last approximately eight hours.

- Visit four: safety check.
  This visit will include a visual fields test and vision measurements and will last approximately one hour.

We anticipate that you will complete the study within three to four months. You will be able to drive to these appointments if you are able, as no dilating eye drops will be used during these visits. Appointments can be made in advance to suit your schedule and a courtesy reminder phone call or email can be arranged before each visit.

End of study

After you have completed your visits, your participation in the study will end. You will be informed of the results of the study once they have been analysed by letter or email. The measurements taken as part of the study will also be recorded in your medical notes at the hospital so that the information we collect about your ocular surface and symptoms can be utilised by the eye doctors when they assess you at subsequent hospital visits. A copy of the measures can also be provided to yourself. You will then continue with your standard of care clinic appointments in the eye clinic as previously planned by the consultant.

We will also inform your General Practitioner (GP) unless you indicate otherwise at the time of your glaucoma clinic visit.

What are the benefits of taking part?

There are no direct benefits of taking part in this study.

Any pre-existing problems with the oil glands may be improved because of using the lid warming goggles. The additional eye pressure measures will be made available to your treating consultant to help with future management of your condition.

The information generated in this study could improve our understanding of treating glaucoma with eye drops and help doctors treat patients more effectively in the future and help to reduce costs to the NHS.

What are the possible disadvantages and risks of taking part?

Most of the tests that are included in this study are straightforward, take seconds to perform, and most are part of your regular eye examination in the clinic. Therefore, there is minimal added risk by involvement in this study as compared to a regular eye examination.

What if something goes wrong?

Any concern about the way you have been treated during the study or any possible harm you might suffer will be addressed. Further detailed information is included in **Part two.**

Will my taking part in this study be kept confidential?
Yes. All the information about your participation in this study will be kept confidential. The details are included in **Part two.**

Will my GP be informed of my participation in this study?
With your permission we will inform your GP of your participation in this study.

Expenses and payments
All tests will be performed free of charge. Payment will be given for participating in the study to cover travel, parking costs and refreshments.

If the information in part one has interested you and you are considering participating please read the additional information in Part two before making a decision.

PART TWO

What will happen if I do not want to carry on with the study?
Participation in this research study is entirely voluntary. Subjects are free to withdraw from the study at any time, without giving a reason and this will not result in any penalty or affect future medical care in any way. You are encouraged to contact the study doctor or study centre should you decide to withdraw your consent. They will explain the best way for you to discontinue your participation in the study. From the moment you withdraw your consent no new data will be collected.

What if there is a problem?
We are not anticipating any side effects from the procedures involved in this study as the majority of the tests are carried out as part of a routine eye clinic appointment. However, we will ask you at each visit if you have any concerns regarding the study and whether you are happy to continue participating. If you are concerned about any aspect of this study outside of the clinic visits, you should ask to speak to one of the researchers who will do their best to answer your questions (details are provided on the front page of this document).

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the **Patients Advice & Liaison Service (PALS):**

Address:
PALS Service
Hinchingbrooke Hospital
Hinchingbrooke Park
Huntingdon
PE29 6NT

TEL: 01480 428964
Email: Hch-tr.pals@nhs.net

OR

Address:
PALS Service,
Department No. 003,
Peterborough City Hospital,
Edith Cavell Campus,
Bretton Gate,
Peterborough,
PE3 9GZ

TEL: 01733 673405
Email: nwangliaft.pals@nhs.net

If something goes wrong and you are harmed during the study owing to someone's negligence then you may have grounds for legal action for compensation against the hospital involved, but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

NHS hospitals are unable to agree in advance to pay compensation for non-negligent harm (situations where no one can be blamed for what happened). However, NHS Trusts are able to consider offering an ex-gratia payment in the case of a claim.

Who is organising and funding this research?
This important research is being funded by Sight Research UK. The trial is sponsored and will be run by NWAFT who have reviewed the research plans and have accepted legal and ethical responsibilities for the trial.

Has this trial been reviewed and approved?
Any research that is conducted within the NHS must follow the strict guidelines and regulations that are in place to ensure patient safety. Research Ethics Committee (**REC**) are an independent group that have approved this trial after ensuring that your safety, rights, well-being, and dignity will not be compromised if you decide to take part.

Have any patients or members of the public been involved in this trial?
When designing this trial, it was important for us to ensure that the comments and suggestions of the public were taken on board, so that we could confirm that this trial was suitable for people with primary open angle Glaucoma or ocular hypertension. To do this, the trial was developed with the help of people diagnosed with Glaucoma in the Cambridgeshire area who agreed that the tests and procedures included in this study were practical and acceptable to patients.

What personal information will we be collecting?
To carry out this research we will need to collect information about you and some of this information will be personal data. Under the data protection law, we must provide you with very specific information about what we do with your data and about your rights. We will need to use information from you and your medical records for this research project. This information will include your name, biological sex, NHS number, date of birth, copies of your eye tests and a short description of your relevant medical history.

Who is the data controller?
NWAFT is the data controller for the personal data that we process in relation to you.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in a specific way for the research to be reliable. If you agree to take part in this

study, you will have the option to take part in future research using data saved from this study. Once we have finished the study, we will keep some of the data so that we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Where can you find out more information about how your information is used?

You can find out more about how we use your information at:
www.hra.nhs.uk/information-about-patients/

What is our legal basis for processing your data?

The legal justification we have under the data protection law for processing your data is that the sponsor is undertaking medical research in the public interest. We do not envisage any problems occurring as a result of your participation in the trial. However, all patients are covered for negligent harm according to the NHS indemnity guidelines. If you have any concerns about any aspect of this trial, please feel free to ask a member of the research ream who will do their best to answer your questions (contact details are on the front of this information leaflet).

How will we use information about you?

We will need to use information from you and your medical records for this research project. People will use this information to do the research or to check your records to make sure that the research is being done properly.

Once we have finished the trial, we will keep some of the data so we can check the results. With your permission we would like to fully anonymise your tests and use them to teach eye specialists in the future. We will write our reports in a way which makes sure that no-one can work out that you took part in the trial.

How will my personal data be kept secure?

All data will be handled in accordance with the General Data Protection Regulations (GDPR) and Data Protection Act 2018. All NWAFT clinic trial databases are held in secure, monitored servers. Access to study data stored at NWAFT will be granted to authorised representatives from the host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections in line with participant consent. Annual security awareness training is mandatory for all staff at NWAFT and is accredited under the NHS information governance toolkit. Any physical paperwork

containing identifiable data will be kept inside a locked filing cabinet, in an access-controlled room within an access-controlled building.

Your rights in relation to your data

Your rights to access, change or move your information are limited, as we need to manage your information in certain ways for the research to be reliable and accurate. You can withdraw your consent to our processing your data at any time. We will store the information about you that we have already obtained if this has already been analysed. In the unlikely event that you lose capacity to consent during the trial you will be withdrawn from the study, any data already collected will still be used for analysis. Should you wish to withdraw from the trial, but do not let the study team know of the type of withdrawal you want, we will assume that you do not want the study team to contact you in the future. If you decide to withdraw and let us know that you do not want us to use your data, then no new analysis will be started using your information. However, we cannot remove your data from any analysis that was completed before your withdrawal from the trial.

Under the provision of the GDPR 2018, you have the right to know the information the study team has recorded about you. If you wish to view this information, please contact Julie Safford on 01480 416015 or email: nwangliaft.hhaccessservices@nhs.net

If you would like more information on your rights, would like to exercise your right or have any queries relating to our processing of your personal data, or if you would like to make a complaint about how your data is being processed, please contact NWAFT Data Protection Officer (DPO) Sean Dykes, email: Sean.Dykes@nhs.net

How long will my personal data be kept?

Your data will be retained for a minimum of 15 years after the publication of the research outcomes. If you withdraw from the project, we will keep the information we have already obtained and processed but, to safeguard your rights, we will collect the minimum amount of information that personally identifies you.

Who will my personal data be shared with?

The personal data that we will collect about you will include your name, date of birth, biological sex, NHS number, and a short description of your relevant medical history. The only people who will see this information are the people who look after

you at your hospital, a very small number of the Ophthalmology trial team at NWAFT who are directly managing the HALO trial, and any representatives from regulatory bodies who need to ensure that the research is being done properly. Relevant aspects of your data will be provided by your clinical care team to the HALO trial team based at NWAFT as necessary, via specifically designed databases. Only your unique trial number will be used as an identifier in any correspondence between your clinical care team and the other institutions where the HALO trial team are based.

The trial team at the NWAFT will store this information on a secure database hosted at the hospital which will produce a unique trial number. This trial number will be used as a link to identify your information for the rest of the trial team.
Staff at your treating hospital will produce copies of your tests that have all your personal information removed and replaced by the unique trial number, which acts as a linker. These tests plus some relevant medical information and your treating clinician's diagnosis will be uploaded onto a computer database based at NWAFT.

What will happen to the results of the research study?
Once the study is complete and the data has been analysed, the results will be submitted for publication in a scientific journal and presented at scientific conferences. Your confidentiality will be maintained and you will not be identified in any report or publication of this study. If you wish to see the results when they are published let the researcher who obtains consent from you know and a copy of the results can be sent or emailed to you.

Who is organising and funding the results?
The study is being organised by Mr. Safdar Alam (Consultant Ophthalmologist), who acts as Chief Investigator for this study, Dr Catherine Willshire (Research Optometrist), who acts as Principal Investigator at NWAFT and Mr. Anthony Nithy (Consultant Ophthalmologist), who acts as a consultant for the study.
The study is funded by a charity called Sight Research UK. The research team conducting the study are not receiving additional payments for including you in this study.

Who has reviewed the study?
The study has been reviewed by the grants panel consisting of glaucoma specialists and lay patient representatives. The documentation associated with the study has been reviewed by the National Institute for Health and Care Research (NIHR)

Patient Research Ambassadors based at NWAFT with members of the R&D team. Leading glaucoma and ocular surface specialists who are collaborating on this study have reviewed the protocol and design of the study.

Thank you for considering taking part in this study.

If you decide to participate you will be asked to sign a consent form and you will be given a copy of the information sheet and consent form to retain in your personal records.