PARTICIPANT INFORMATION LEAFLET
(Version 5.1 – 30.9.2019)

Title of Project:
Does pre-operative D-chart score predict improvement in VFQ-25 score following surgery for epiretinal membrane?
Short Title:
Distortion as a predictor of ERM surgery outcome

Sponsor Protocol Number: GN18OP439
IRAS Project ID: 246530

Chief Investigator: Dr David Yorston

You are being invited to take part in a research study. Before you decide it is important for you 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 friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

The purpose of this study is to investigate whether it is possible to predict, from simple measurements made in clinic, which patients will experience a benefit from having surgery for epiretinal membrane.

Epiretinal membrane surgery:

The retina is a thin layer which lines the back of the eye. It is sensitive to light (like the film in a camera) and is necessary for vision. If an epiretinal membrane develops on the surface of the retina, it can cause wrinkling and swelling of the retina which will in turn cause

blurred or distorted vision.

This epiretinal membrane can be removed through an operation. During this operation, we insert instruments into the back of the eye (like keyhole surgery) and peel off this membrane from the surface of the retina. We sometimes leave an air or gas bubble in the eye which is gradually absorbed by the eye over a few days or weeks.

***Distortion before and after epiretinal membrane surgery**:*

Epiretinal membranes can affect eyesight by causing blurred vision and also by causing distortion (straight lines appearing bent or wiggly) and this might eventually have an impact on lifestyle, e.g. affecting hobbies, driving etc. If the symptoms are quite mild the patient might not wish any intervention for this. However, if the epiretinal membrane is causing troublesome symptoms, the patient is offered surgery.

At the moment we don't know which of the patients referred to our clinic with epiretinal membrane are most likely to experience a positive effect on their lifestyle from having surgery. Through our study we are aiming to collect data before and after the operation and work out whether we can identify any factors from the pre-operative measurements that help us predict how successful the operation will be. This will help us in the future to advise patients about the likelihood of success with an operation and help the surgeon and patient make a joint decision.

Why have I been chosen?

You have been chosen because you have an epiretinal membrane and have decided to have an operation to have this removed.

Initially we hope to study 65 patients with this condition.

What will happen to me if I take part?

The surgery you receive to remove the epiretinal membrane will be the same as if you were not in the study. The only difference will be the extra measurements that we will take before and after the operation. Therefore we will be observing the effects of the surgery rather than influencing the treatment.

In addition to the usual tests, which include measurement of vision and imaging of the retina, we will measure the level of distortion in each eye using a chart – this takes between 5-10 minutes. We will also ask each participant to fill in a questionnaire to assess how their level of vision is affecting their quality of life. These measurements will be repeated at 6 and 12 months after the operation, as some patients can continue to experience improvement in their eyesight over this period.

If you would like, we could send an information letter to your GP to inform them of your participation in this study, with your consent.

What will happen to me at each clinic visit?

By participating in this study, you will be asked to attend the clinic:

1) Before the operation
2) Two weeks after your operation
3) Six months after your operation
4) One year after your operation

At each visit, your vision will be checked and the doctor will examine your eye as usual with a microscope.

At pre-operative visit and 6-month and 1-year post-operative visits, there will be a few additional tests:

- Routine scan (OCT) of the back of your eye. This is completely painless and harmless and does not involve radiation. [Duration: 3 minutes]

- Measurement of amount of visual distortion using a chart. [Duration: 5 minutes]
- You will be asked to complete a questionnaire that assesses the impact of your eyesight on your quality of life and mood [Duration: Fifteen minutes]

What are the side effects of taking part?

Epiretinal membrane surgery has some possible risks or side effects. These include changes in the pressure in the eye, infection, retinal detachment, and developing cataract (clouding of the nature lens).

Some people continue to experience some amount of blurred vision and distortion following the surgery. We don't know who is likely to benefit or not from this surgery and this is what we are investigating.

What are the possible benefits of taking part?

All patients in the study will receive standard surgical care and we will only be measuring the outcome rather than influencing it in any way.

Do I have to take part?

No. It is up to you to decide whether or not to take part.

If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form.

Even after this, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive. If

you do not wish to take part in this study you will not be at a disadvantage and will continue to receive normal clinical management.

What happens when the research study finishes?

If you still require follow-up for your eye condition, this will be continued routinely in the out-patient department, and not as part of the study in the Clinical Research Facility.

What will happen to the results of the study?

We plan to publish the results of this study in a medical journal, and if you like, we can give you information about how to access this material. Please remember that as there are 65 participants in the study, it might take a couple of years before this information is available.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms may be available to you.

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the Complaints Department for NHS Greater

Glasgow and Clyde Hospitals by phone or email (see Contact Section below for details).

Who is organising and funding the research?

This study is sponsored by NHS Greater Glasgow and Clyde and has received funding from the Royal College of Surgeons of Edinburgh.

Will there be any reimbursement available for travel or parking?

No.

Will my taking part in this study be kept confidential?

NHS Greater Glasgow and Clyde is the sponsor for this study based in Glasgow. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. NHS Greater Glasgow and Clyde will keep identifiable information about you for 5 years. If and when it is disposed of, this will be done securely in line with Trust policy.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Information collected from the study will be treated as completely confidential. Research data collected from you such as your age, medical history and clinical examination findings will be anonymised. We will issue you with a unique study ID number which will appear on

research documents instead of your name. The anonymised paper records will be stored in a locked room, with secure access. All electronic data storage will comply with the requirements of the General Data Protection Regulation (GDPR).

You can find out more about how we use your information by contacting our Data Protection Officer (see Contact Section below).

Who has reviewed the study?

A full scientific protocol for this research has been approved by the Clinical Research and Development Department in NHS Greater Glasgow and Clyde and by the North of Scotland Research Ethics Committee.

What happens if I lose capacity to consent during the study?

If you lose capacity to consent during the study, we would withdraw you from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected and no other research procedures would be carried out in relation to you.

Thank you for considering taking part in this study.

Contact Numbers:

Chief Investigator
Dr. David Yorston
Consultant Ophthalmologist **0141 211 1041**

Research Coordinator
Dr Margaret Fegen **0141 201 9329**

Health-related Emergency **0141 211 1033**

Complaints Department, NHS Greater Glasgow and Clyde:
0141 201 4500
complaints@ggc.scot.nhs.uk

Data Protection Officer : **Isobel.Brown@ggc.scot.nhs.uk.**

You will be given a copy of this information sheet and the consent form, which you have signed, to keep. The original will be retained in your clinical notes.