

A pilot randomised masked study of ILM peeling with the new Grieshaber Sharkskin forceps as compared to the existing Grieshaber finesse forceps: the PRECISE study

Submission date 19/08/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/09/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/07/2023	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Macular holes (MH) are approximately half millimetre round defects in the very centre of the retina that form in some people as a result of age and result in loss of central vision and blindness. In 1991 it was shown that vitrectomy surgery could result in closure of the hole and improvement in vision and it is now one of the most common indications for retinal surgery with over 2500 operations carried out annually in the UK alone.

During the surgery the internal limiting membrane (ILM) of the retina is routinely peeled off as this has been shown to improve the results of surgery. The ILM is a very fine 5-micron thick membrane and is peeled with specially designed forceps. When the membrane is peeled the inner surface of the retina can be damaged and some of these changes have been linked to where the forceps grasps the ILM during the peeling procedure.

A new pair of forceps have been developed and CE marked to specifically improve the ease of picking up the ILM which should reduce any damage to the retina, but it is not known if this will definitely occur. We propose a feasibility study to analyse the effects of ILM peeling in a pilot randomised controlled trial of 66 patients undergoing ILM peeling for macular holes with conventional ILM peeling forceps that have been used for several years as compared to the new Forceps.

The study will concentrate on objective signs of retinal injury but will also assess surgeon related factors in a questionnaire as well as visual acuity and visual fields after surgery. Surgeons, postoperative vision and imaging assessors will be masked to the type of forceps used to reduce bias. The study will help inform a future full scale RCT of the use of the forceps.

Who can participate?

Patients aged 50 years or older with a primary idiopathic macular hole of any size and less than 12-month duration

What does the study involve?

At the time of surgery participants will be randomised to either the new forceps or the existing

ones. The patient will then have the surgery exactly as is routinely carried out but at the time for the ILM to be peeled the surgeon will be given the randomised type of forceps to use. The follow up after surgery will be as routinely carried out and the patient will be seen at 3 weeks, 3 months and 6 months post-operatively

What are the possible benefits and risks of participating?

There are no clear benefits to patients taking part at this stage. We will evaluate the efficacy of the new forceps against the existing forceps in order to establish whether there is any superiority in terms of clinical benefit to patients and performance for the surgeon. If we find superiority, this would indicate a potential benefit to future patients either directly (better recovery) or indirectly (surgeons find forceps better to use) or both. Should there actually prove to be inferiority for whatever reason, then future patients would benefit from the recommendation to remain using existing forceps rather than upgrading to the new version. The risk to patients is minimal as the forceps are being utilised in keeping with their CE marked intended use.

Where is the study run from?

1. Sunderland Royal Hospital, UK
2. Freeman Hospital, UK
3. Royal Liverpool Hospital, UK

When is the study starting and how long is it expected to run for?

October 2019 to November 2020

Who is funding the study?

Alcon, USA

National Institute for Health Research (NIHR), UK

Who is the main contact?

David Steel,

David.Steel@ncl.ac.uk

Phil Mawson,

philip.mawson@ncl.ac.uk

Contact information

Type(s)

Scientific

Contact name

Mr Phil Mawson

Contact details

Newcastle University

William Leech Building

Medical School

Framlington Place

Newcastle upon Tyne

United Kingdom

NE2 4HH
+4419120824225
philip.mawson@ncl.ac.uk

Type(s)

Scientific

Contact name

Mr David Steel

Contact details

Sunderland Eye Infirmary
Queen Alexandra Road
Sunderland
United Kingdom
SR2 9HP
+44191 241 8816
David.Steel@ncl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

42671

Study information

Scientific Title

Peeling of the ILM from the retinal surface with finesse forceps; the PRECISE study

Acronym

PRECISE

Study objectives

Feasibility study to analyse the effects of internal limiting membrane (ILM) peeling in a pilot randomised controlled trial of 66 patients undergoing ILM peeling for macular holes with conventional ILM peeling forceps that have been used for several years as compared to the new Grieshaber Sharkskin forceps

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 31/07/2019, North of Scotland Research Ethics Committee 1 (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE; +441224 558458; nosres@nhs.net), ref: 19/NS/0124

Study design

Randomised; Interventional; Design type: Treatment, Surgery

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Macular holes

Interventions

Only patients who have been placed on the waiting list for primary macular hole surgery will be approached. The study will be explained to them and if they are eligible and agree to participate, they will be consented. The first study activity will be to have their vision very carefully assessed and a visual field test performed. They will also have scans performed of their retina which is already part of standard care.

At the time of surgery they will be randomised to either the new forceps or the existing ones. The person with the macular hole will then have the surgery exactly as is routinely carried out but at the time for the ILM to be peeled the surgeon will be given the randomised type of forceps to use. The forceps look virtually identical - the difference is a microscopic laser etched pattern on their tips which makes it easier to pick up the ILM - and so the surgeon will not be able to tell the difference. The surgery will be video as routinely carried out but the video will be anonymised and sent to another surgeon who will be masked to the type of forceps and they will grade various aspects of the peeling procedure. The surgeon will also be asked to fill in a questionnaire about how the ILM was peeled and the ease of the procedure.

The follow up after surgery will be as routinely carried out and the patient will be seen at 3 weeks, 3 months and 6 months post-operatively. At all visits the patients will have scans done of the retina as routinely carried out but these scans will be sent to a reading centre in Belfast (network UK) where trained graders will grade the amount of retina trauma on the scans. At the 3 month visit the patient will also have a careful test of visual acuity and visual fields and the results sent to the research team. At the 3 week and 6 month visit the visual acuity will be checked in the normal way and sent to the research team.

Six surgeons across three centres (2 at each) will take part in the study- all will be experienced retinal surgeons who have performed at least 70 macular hole operations.

Intervention Type

Other

Primary outcome(s)

Recruitment and retention rate recorded as the number of eligible participants who consent to participate in the study over a four-month recruitment period and complete patient schedule in adherence to protocol

Key secondary outcome(s)

1. Inner retinal changes measured by standard visual acuity assessments, eye imaging and recording of any adverse events post-surgery at 3 weeks, 3 month and 6-month time points
2. Surgeon perception of device performance during ILM procedure measured by the study questionnaire completed immediately after surgery

Completion date

17/11/2020

Eligibility

Key inclusion criteria

1. Primary idiopathic macular hole of any size and less than 12-month duration
2. Other previous treatments (gas, OCP) allowed
3. Full comprehension of study requirements at time of consent (at discretion of clinician)
4. Aged 50 years or older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

65

Key exclusion criteria

1. ILM peeling not planned
2. MH secondary to other causes including trauma, previous retinal detachment
3. Previous vitrectomy surgery
4. Previous significant macular disease affecting visual acuity (mild early or intermediate AMD allowed)
5. Advanced glaucoma
6. Known vision affecting optic nerve disease
7. Diabetic retinopathy of more than R1 including previously treated PDR
8. Significant intraocular inflammation
9. Myopia > -6 dioptres or axial length > 26mm
10. Amblyopia of less than ~6/18
11. Conditions affecting ability to perform visual fields or imaging
12. Participation in any other clinical/interventional trial that may impact study findings

Date of first enrolment

01/10/2019

Date of final enrolment

01/05/2020

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Sunderland Royal Hospital

Kayll Road

Sunderland

United Kingdom

SR4 7TP

Study participating centre

Royal Victoria Infirmary

Queen Victoria Road

Newcastle upon Tyne

United Kingdom

NE1 4LP

Study participating centre

Royal Liverpool Hospital

Prescot Street

Liverpool

United Kingdom

L7 8XP

Sponsor information

Organisation

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Industry

Funder Name

Alcon; Grant Codes: #38075469

Alternative Name(s)

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2023	10/07/2023	Yes	No
HRA research summary			28/06/2023	No	No