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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

Registration date
06/09/2019

Overall study status
Completed

Last Edited
10/07/2023

Condition category
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 of 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 of 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 anonimised 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 (networc 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 measure
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

Secondary outcome measures
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

Overall study start date
01/04/2019

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 66; UK Sample Size: 66

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
England

United Kingdom

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
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L7 8XP

Sponsor information

Organisation
The Newcastle Upon Tyne Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/03/2022

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?
HRA research summary			28/06/2023	No	No
Results article		01/06/2023	10/07/2023	Yes	No