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Full thickness macular hole and Internal Limiting Membrane (ILM) peeling Study: a randomised comparison of macular hole surgery with or without internal limiting membrane peeling

Submission date
02/08/2005

Recruitment status
No longer recruiting

Registration date
21/09/2005

Overall study status
Completed

Last Edited
17/08/2018

Condition category
Eye Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.charttrials.abdn.ac.uk/films

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00286507

Secondary identifying numbers
HS028 RGC1462

Study information

Scientific Title
Full thickness macular hole and Internal Limiting Membrane (ILM) peeling Study: a randomised comparison of macular hole surgery with or without internal limiting membrane peeling

Acronym
FILMS

Study objectives
The principal research question is whether peeling the internal limiting membrane of the retina improves the vision of patients undergoing macular hole surgery. Secondary questions are whether peeling the internal limiting membrane of the retina improves the anatomical outcome of macular hole surgery and, subsequently, the quality of life of patients with macular holes. Whether internal limiting membrane peeling is cost-effective will also be considered.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: https://medserv.abdn.ac.uk/films/documents/pdf/patientInformationSmPdf.pdf

Health condition(s) or problem(s) studied

Full-thickness macular holes in the centre of the retina

Interventions
Participants will undergo one of the two possible macular hole surgeries:
1. Surgery without ILM peeling
2. Surgery with ILM peeling

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Distance visual acuity at 6 months post surgery.

Secondary outcome measures
Distance visual acuity at 3 months, near visual acuity at 3 and 6 months, contrast sensitivity at 6 months, reading speed at 6 months, health related quality of life, costs to the health service and the participant, incremental costs per QALY and adverse events.

Overall study start date
01/06/2005

Completion date
31/05/2008

Eligibility

Key inclusion criteria
Patients with idiopathic full-thickness macular holes (FTMHs) stages 2-3 of equal to or less than 18 months duration and with vision equal to or worse than 20/40 in the study eye.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria

Patients with macular holes of stage 1 or 4 or with a hole of greater than 18 months duration will be excluded. If the FTMH is related to high myopia or trauma or there are other causes of decreased vision (e.g. corneal scarring, age-related macular degeneration, diabetic retinopathy, glaucoma if central and/or paracentral absolute visual field defects are present) will also be excluded. Patients who are unable to understand English or give informed consent to be excluded.

Date of first enrolment
01/06/2005

Date of final enrolment
31/05/2008

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Eye Clinic, Foresterhill
Aberdeen
United Kingdom
AB25 2ZN

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
Kings College
Aberdeen
Scotland
United Kingdom
AB24 3FX

Sponsor type
University/education

Website
http://www.abdn.ac.uk

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Health Department, Scottish Executive (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/11/2008		Yes	No
Results article	results	01/03/2011		Yes	No