

# 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

<b>Submission date</b> 02/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/08/2018	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> 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?
<a href="#">Protocol article</a>	protocol	03/11/2008		Yes	No
<a href="#">Results article</a>	results	01/03/2011		Yes	No