

# Positioning in macular hole surgery

<b>Submission date</b> 11/02/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/02/2015	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/05/2020	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A macular hole is a small gap that occurs at the centre of the retina (a thin light-sensitive layer of tissue lining the inner surface of the eye). The condition causes sight loss in approximately 2 in every 1000 individuals and can have a devastating impact on quality of life and independence. The condition is believed to result from pulling on the retina by the vitreous gel that fills the eye. It is treated by surgical removal of the vitreous gel to relieve these forces, and injection of a gas bubble to help close the hole. Following surgery, patients may be advised to maintain a face-down position (with the eyes directed straight down) for up to 10 days. This aims to improve the likelihood of the hole closing successfully by maintaining contact of the gas bubble with the macular hole. However, face-down positioning can be uncomfortable and we do not know if it is actually required to ensure a successful outcome. The aim of this study is to determine the value of the advice to position face-down following surgery for large macular holes.

### Who can participate?

Adults (aged over 18) diagnosed with a large macular hole

### What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 are advised to position themselves face-down for 8 hours a day for 5 days. Those in group 2 are advised to adopt an inactive face-forward position for a similar period.

### What are the possible benefits and risks of participating?

The study will benefit patients by providing reliable information on the value of positioning following surgery for large macular holes, thereby enabling them to make an appropriately informed choice about the management of their condition.

### Where is the study run from?

Moorfields Eye Hospital NHS Foundation Trust (lead centre) and 5 other NHS hospitals in the UK.

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

November 2014 to December 2017

### Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?  
Dr James Bainbridge

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr James Bainbridge

**Contact details**  
Moorfields Eye Hospital NHS Foundation Trust  
162 City Road  
London  
United Kingdom  
EC1V 2PD

## Additional identifiers

**Protocol serial number**  
17966

## Study information

**Scientific Title**  
A multicentre interventional comparative randomised controlled clinical trial comparing face-down positioning with an inactive face-forward position on the outcome of surgery for large macular holes

**Study objectives**  
The aim of the proposed research is to determine the value of advice to position face-down following surgery for large macular holes.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
NRES Committee London - Westminster, 09/01/2015, ref: 201514/LO/2061

**Study design**  
Randomised; Interventional; Design type: Treatment

**Primary study design**  
Interventional

**Study type(s)**  
Treatment

## Health condition(s) or problem(s) studied

Topic: Ophthalmology; Subtopic: Eye (all Subtopics); Disease: Ophthalmology

## Interventions

Positioning in macular surgery. The intervention is advice to position face-down following surgery for a total of at least 8 consecutive or non-consecutive hours daily for 5 days. The comparison is advice to maintain an inactive face-forward position following surgery for a total of at least 8 consecutive or non-consecutive hours a day for 5 days.

## Intervention Type

Other

## Primary outcome(s)

Anatomical closure of the macular hole; Timepoint(s): Determined at three months after surgery by masked assessment of OCT scans.

## Key secondary outcome(s)

To determine the impact of face-down positioning on sight, quality of life and wellbeing.

## Completion date

31/12/2017

## Eligibility

### Key inclusion criteria

1. Presence of idiopathic full-thickness macular hole, greater than or equal to 400  $\mu\text{m}$  in diameter as measured OCT
2. Patients electing to have surgery for macular hole, with or without simultaneous phacoemulsification and intra-ocular lens implant
3. Ability and willingness to position face-down or in an inactive faceforward position
4. Lower age limit 18 years

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Total final enrolment

185

## **Key exclusion criteria**

1. Age-related macular degeneration; glaucoma; diabetic retinopathy; retinal degeneration; amblyopia; previous vitrectomy surgery (refractive error, lens opacity and previous use of ocriplasmin are not exclusion criteria)
2. Traumatic macular hole
3. History of visual loss suggesting macular hole duration longer than 12 months
4. Presence of a retinal tear identified during surgery for which post operative positioning is advised

## **Date of first enrolment**

01/05/2015

## **Date of final enrolment**

01/04/2017

## **Locations**

### **Countries of recruitment**

United Kingdom

England

Scotland

### **Study participating centre**

**Moorfields Eye Hospital NHS Foundation Trust (lead centre)**

162 City Road

London

United Kingdom

EC1V 2PD

### **Study participating centre**

**Gartnavel General Hospital**

Glasgow

United Kingdom

G12 0YN

### **Study participating centre**

**Maidstone Hospital**

Kent

United Kingdom

ME16 9QQ

**Study participating centre**  
**Manchester Royal Eye Hospital**  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Sunderland Royal Hospital**  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**  
**Whipps Cross Hospital**  
London  
United Kingdom  
E11 1NR

## **Sponsor information**

**Organisation**  
Moorfields Eye Hospital NHS Foundation Trust

**ROR**  
<https://ror.org/03zaddr67>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
National Institute for Health Research

**Alternative Name(s)**  
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**  
Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## 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="#">Results article</a>	results	01/07/2020	07/05/2020	Yes	No
<a href="#">Protocol article</a>	protocol	17/11/2015		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Statistical Analysis Plan</a>	statistical analysis plan	13/06/2017		No	No