

# Pilot RCT of posturing following surgery for macular hole

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/12/2011	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N0141187718

## Study information

**Scientific Title**

**Study objectives**

1. To estimate variance and effect size in order to inform power calculations that will determine the design and size of a future study
2. To estimate recruitment and therefore duration of a future study
3. To establish procedures and protocols for the future study

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Pilot randomised controlled study

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Eye Diseases: Macular hole

**Interventions**

1. Posture face down for 50 minutes in every hour for the first 10 days after operation
2. Not to maintain specific posture, except avoid face up posture

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. Variance and effect size to inform power calculation for a full study
2. Recruitment rate
3. Establish procedures and protocols

**Key secondary outcome(s)**

1. Macular hole closure
2. Visual acuity
3. Complications
4. Differences in answer to patient survey questions between the 2 groups

**Completion date**

15/11/2007

**Eligibility****Key inclusion criteria**

1. Patients listed for surgery for idiopathic full thickness macular hole
2. Able and willing to posture face down for 10 days postoperatively
3. Agree to participate in the trial and give informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**Key exclusion criteria**

1. History of visual loss suggesting a duration of macular hole > 12 months
2. Patients unwilling or unable to posture face down for 10 days postoperatively
3. History of trauma which may have been causative
4. Age less than 18 years old in UK or less than 16 years old in Scotland
5. Previous vitrectomy surgery

**Date of first enrolment**

15/11/2006

**Date of final enrolment**

15/11/2007

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Moorfields Eye Hospital**

London

United Kingdom

EC1V 2PD

**Sponsor information**

**Organisation**

## Funder(s)

### Funder type

Government

### Funder Name

Moorfields Eye Hospital NHS Foundation Trust

### Funder Name

NHS R&D Support Funding

## 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	07/12/2011		Yes	No