# Pilot RCT of posturing following surgery for macular hole

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
28/09/2007		☐ Protocol		
Registration date 28/09/2007	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
20/12/2011	Eye Diseases			

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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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?
Results article	results	07/12/2011		Yes	No