

Pilot RCT of posturing following surgery for macular hole

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

15/11/2006

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

30

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

England

United Kingdom

Study participating centre

Moorfields Eye Hospital

London

United Kingdom

EC1V 2PD

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

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Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Moorfields Eye Hospital NHS Foundation Trust

Funder Name

NHS R&D Support Funding

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?
Results article	results	07/12/2011		Yes	No