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Pilot RCT of posturing following surgery for macular hole

Submission date	Recruitment status	[_] Prospectively registered
28/09/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/09/2007	Completed	[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
Mr W Luke Membrey

Contact details
Moorfields Eye Hospital
162 City Road
London
United Kingdom
EC1V 2PD
+44 (0)20 7566 2059
Luke.Membrey@moorfields.nhs.uk

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

Primary study design
Interventional

Study design
Pilot randomised controlled study

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

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

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