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Positioning in macular hole surgery

Submission date
11/02/2015

Recruitment status
No longer recruiting

Registration date
11/02/2015

Overall study status
Completed

Last Edited
08/05/2020

Condition category
Eye Diseases

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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 in 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

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

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

Overall study start date
01/11/2014

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Presence of idiopathic full-thickness macular hole, greater than or equal to 400 µm 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 192; UK Sample Size: 192; Description: 192 patients in total, 96 in each arm of the study (SS incorporates 10% loss to follow up -min. requirement 86 per arm, 172 in total)

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
England

Scotland

United Kingdom

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

Sponsor details

162 City Road
London
England
United Kingdom
EC1V 2PD

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
The results will be disseminated at clinical meetings, and by publication in a peer-reviewed journal. A lay summary will be published on the trial website at: http://blizard.qmul.ac.uk /research-generation/870-macular-hole-positioning.html and should be available from summer 2017.

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?
Protocol article	protocol	17/11/2015		Yes	No
Statistical Analysis Plan	statistical analysis plan	13/06/2017		No	No
Results article	results	01/07/2020	07/05/2020	Yes	No
HRA research summary			28/06/2023	No	No