

Positioning after idiopathic macular hole surgery

Submission date 02/01/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/01/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/07/2008	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
N/A

Study information

Scientific Title

Comparison of face-down and seated position after idiopathic macular hole surgery

Study objectives

To test whether a face-down position is required in every patient operated on idiopathic macular hole, whatever the size of the macular hole.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee for Protection of Human Subjects in Biomedical Research, Bourgogne (Comité Consultatif de protection des personnes dans la recherche biomédicale de Bourgogne). Date of approval: 6 May 2004 (ref: 2004/26)

Study design

Prospective, comparative, randomized controlled trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Idiopathic macular hole

Interventions

All patients are subjected to the same surgical procedure: an extensive three-port pars plana vitrectomy using 20-gauge instrumentation. A peristaltic or venturi pump is used with maximum vacuum set between 200 and 500 mmHg according to the surgeon's preference, to obtain posterior vitreous detachment. The posterior hyaloid is removed. Then the Internal Limiting Membrane (ILM) is systematically removed using microforceps without indocyanine green or any other dye. Vitrectomy is completed, especially at the vitreous base. Finally, total FluidAir Exchange (FAE) was performed and a nonexpanding mixture of air and SF6 (20%) is used for pneumatic tamponade in Idiopathic Macular Holes (IMHs) less than 500 µm, air and C2F6 (17%) in IMHs larger than 500 µm, and air and C3F8 (14%) in IMHs larger than 800 µm.

After there procedures, the patients were allocated to two groups. The P0 group is asked to keep a seated position and P1 patients a strict face-down position 8 h a day for 5 days.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Anatomical closure of the hole after one surgical procedure confirmed by OCT. Timepoints of assessment: before, 3 and 6 months after the surgery.

Secondary outcome measures

Best corrected visual acuity change between the preoperative and the 6-month visit (expressed as LogMAR)

Overall study start date

01/07/2004

Completion date

01/02/2006

Eligibility**Key inclusion criteria**

Patients with stage 2, 3 and 4 idiopathic macular holes according to a scale developed by Gass and confirmed by Optical Coherence Tomography (OCT)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

140 patients

Key exclusion criteria

1. Axial length longer than 27 mm
2. Previous macular surgical procedure
3. Stage I macular holes
4. Posttraumatic or other secondary macular holes
5. Inability to assume a correct face-down position

Date of first enrolment

01/07/2004

Date of final enrolment

01/02/2006

Locations

Countries of recruitment

France

Study participating centre

Service d'Ophtalmologie

Dijon

France

21000

Sponsor information

Organisation

Burgundy Association for Research in Ophthalmology (ABPRO) (France)

Sponsor details

Service d'Ophtalmologie

University Hospital Dijon (CHU) General Hospital

Dijon

France

21000

Sponsor type

Research organisation

Website

<http://www.chu-dijon.fr/index.htm>

Funder(s)

Funder type

Research organisation

Funder Name

Burgundy Association for Research in Ophthalmology (ABPRO) (France)

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	01/07/2008		Yes	No