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Positioning after idiopathic macular hole surgery

Submission date	Recruitment status	[_] Prospectively registered
02/01/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/01/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/07/2008	Eye Diseases	

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
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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