

The learning curve for vitreous surgery

Submission date 04/01/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/01/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/01/2008	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

The learning curve for primary vitrectomy without scleral buckling for pseudophakic retinal detachment

Study objectives

Pseudophakic retinal detachment is a complication in patients after cataract surgery. Although rare, this represents a high number of patients since the number of cataract extractions is on the rise (500,000 in France). This complication may lead to a severe loss of visual acuity.

In this study we aim to evaluate the learning curve of junior surgeons in performing primary vitrectomy without scleral buckling for pseudophakic retinal detachment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee for the Protection of Human Subjects in Biomedical Research, Bourgogne (Comité Consultatif de Protection des Personnes dans la Recherche Biomédicale de Bourgogne).
Date of approval: 4 March 2004 (ref: 2004/19)

Study design

Retrospective interventional case series in two academic centers.

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Pseudophakic retinal detachment

Interventions

Surgical procedure with pars plana vitrectomy under local anesthesia. Drainage of subretinal fluid through the retinal break or a retinotomy. External cryotherapy on the retinal tears. At the end of the procedure, air-gas exchange with inexpandable gas mixture. No scleral buckling added.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Reattachment rate with a single procedure at 6-month follow-up

Secondary outcome measures

1. Number of final successes
2. Number of reoperations and complications

Overall study start date

01/05/2004

Completion date

30/04/2006

Eligibility

Key inclusion criteria

Patients presenting with a pseudophakic retinal detachment and a Proliferative VitreoRetinopathy (PVR) grade A and B

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

280

Key exclusion criteria

Patients presenting with a pseudophakic retinal detachment and a PVR grade C and D

Date of first enrolment

01/05/2004

Date of final enrolment

30/04/2006

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
CHU General Hospital
Dijon
France
21000

Sponsor type

Research organisation

Website

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Dijon (CHU), General Hospital (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