ISRCTN31177220 https://doi.org/10.1186/ISRCTN31177220

Assessment of retinal function before and after idiopathic macular hole surgery

Submission date
14/11/2012

Recruitment status
No longer recruiting

Registration date
27/11/2013

Overall study status
Completed

Last Edited
27/11/2013

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Idiopathic macular hole (a small gap that opens up at the centre of the retina, in an area called the macula) causes central vision loss in the elderly. The aim of the study is to assess the effectiveness and safety of pars plana vitrectomy (a surgical procedure that involves removal of vitreous gel from the eye) and internal limiting membrane peeling assisted by intravitreal injection of triamcinolone acetonide or infracyanine green.

Who can participate?
Patients of any age and gender affected by full thickness idiopathic macular hole can participate.

What does the study involve?
Patients are randomly allocated to one of two groups. One group is treated with pars plana vitrectomy and internal limiting membrane peeling assisted by intravitreal injection of triamcinolone acetonide. The second group is treated with pars plana vitrectomy and internal limiting membrane peeling assisted by intravitreal injection of infracyanine green. Retinal function is assessed in patients of both groups before and after the operation.

What are the possible benefits and risks of participating?
The expected benefits of surgical treatment are the closure of the hole with improvement in vision. Possible risks related to the surgical procedure are eye infection, vitreous haemorrhage (leakage of blood into the areas in and around the vitreous humor of the eye), retinal tears and /or detachment.

Where is the study run from?
Department of Opthalmology, Catholic University of Sacro Cuore (Italy).

When is the study starting and how long is it expected to run for?
The study started in December 2010 and the study ran until July 2012.

Who is funding the study?
Catholic University of Sacro Cuore (Italy)

Who is the main contact?
Dr Edoardo Abed

Contact information

Type(s)
Scientific

Contact name
Dr Edoardo Abed

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Assessment of retinal function before and after idiopathic macular hole surgery: a randomised trial

Study objectives
To compare functional outcomes of vitrectomy and internal limiting membrane peeling assisted by intravitreal injection of triamcinolone acetonide or infracyanine green for idiopathic macular hole.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Catholic University of Sacro Cuore Ethics Committee, 08 November 2010

Study design
Randomised interventional treatment trial

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Idiopathic macular hole

Interventions
Patients were divided in two arms of 15 patients each.

Patients of the first arm underwent pars plana vitrectomy and internal limiting membrane peeling assisted by intravitreal injection of triamcinolone acetonide.

Patients of the second arm underwent pars plana vitrectomy and internal limiting membrane peeling assisted by staining with infracyanine green.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Visual acuity measured with Snellen chart before surgery, 7 days and 1, 3, 6 and 12 months after surgery.
2. Anatomical outcomes and macular hole closure evaluated by spectral domain optical coherence tomography.
3. Focal electroretinography of the central 2 and 16 degrees of the retina measured before surgery, 1 and 7 days and 1, 3, 6 and 12 months after surgery.

Secondary outcome measures
Fundus microperimetry with MP-1 before surgery and 1, 3, 6 and 12 months after surgery

Overall study start date
01/12/2010

Completion date
31/07/2012

Eligibility

Key inclusion criteria
Full thickness idiopathic macular hole (stage II, III or IV of Gass Classification) diagnosed and staged by slit-lamp fundus examination, using a 90-diopter lens and spectral domain optical coherence tomography

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Visual acuity worse than 1.0 (logMAR)
2. Previous macular surgery
3. Corneal opacities
4. Macular diseases other than macular hole
5. Optic nerve atrophy
6. Phakic patients

Date of first enrolment
01/12/2010

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
Italy

Study participating centre
Largo Agostino Gemelli
Rome
Italy
00168

Sponsor information

Organisation
Catholic University of Sacro Cuore (Italy)

Sponsor details
Largo Agostino Gemelli, 8
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Sponsor type
University/education

Website
http://www.unicattolica.it/

ROR
https://ror.org/03h7r5v07

Funder(s)

Funder type
University/education

Funder Name
Catholic University of Sacro Cuore (Italy)

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