

Assessment of retinal function before and after idiopathic macular hole surgery

Submission date 14/11/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/11/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/11/2013	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 intracyanine 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 intracyanine 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 Ophthalmology, 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

Contact details

Largo Agostino Gemelli

8 Department of Ophthalmology Catholic University of Sacro Cuore

Rome

Italy

00168

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 intracyanine 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
Rome
Italy
00168

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