

In vivo near-infrared fluorescence imaging of aqueous humor outflow structures

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| Submission date 05/02/2016 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 12/02/2016 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 20/06/2016 | Condition category Eye Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Chronic glaucoma, also known as primary open-angle glaucoma (POAG) is an eye condition which develops when a fluid inside the eye (called the aqueous humor) cannot drain properly, causing pressure (intraocular pressure, or IOP) to build up that can result in damage to the optic nerve and nerve fibres from the retina. It often affects both eyes, generally with one being more affected than the other, and, over time, it can lead to a partial or complete loss of sight. Canaloplasty is a surgical procedure used to treat POAG. It uses a micro-catheter (a tiny tube) to open up the drainage system of the eye (Schlemm's canal). A sterile, gel-like material (viscoelastic) is then used to open up this canal. The micro-catheter is then removed and a suture threaded through the canal, thus opening it and allowing the IOP to drop to a more normal level. This study aims to look at the flow of the aqueous humor through the eye (aqueous outflow system) using a solution containing viscoelastic and indocyanine green (ICG), to take near-infrared fluorescence images of the inside of the eye.

Who can participate?

Adult patients with POAG being treated with canaloplasty.

What does the study involve?

For each participant in the study, a solution made up of of indocyanine green (ICG) and viscoelastic is injected was injected through a microcatheter into the Schlemm's canal . Visualization of the outflow pathway is then accomplished using a microscope with filters working in the range of infrared wavelenghts (~ 800 nm). This imaging then can be used to assess the success of the surgery.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

San Giuseppe Moscati Hospital and the University of Molise (Italy)

When is the study starting and how long is it expected to run for?

May 2015 to November 2015

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Professor Ciro Costagliola
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
In vivo near-infrared fluorescence imaging of aqueous humor outflow structures: a prospective, open, observational single center pilot study

Study objectives
To visualize the aqueous outflow system in patients affected by primary open angle glaucoma that have undergone canaloplasty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective open observational single-center pilot study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Primary open angle glaucoma (POAG)

Interventions

A solution composed of indocyanine green (ICG) and viscoelastic was injected into the Schlemm's canal using the microcatheter during surgery. Visualization of the tracer was accomplished using the microscope PENTERO 900. The progression of the dye along the Schlemm's canal was visualized. The filling of collector channels was observed only in correspondence of the patent portions of the Schlemm's canal.

Intervention Type

Procedure/Surgery

Primary outcome(s)

In vivo visualization of the outflow pathway, using the OPMI PENTERO 900 microscope, measured during surgery

Key secondary outcome(s)

Assessment of the working and non working portions of the conventional outflow pathway on the basis of the visualization of the portion filled, measured during surgery

Completion date

30/11/2015

Eligibility**Key inclusion criteria**

Adult patients affected by POAG undergoing canaloplasty

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Narrow or closed iridocorneal angle
2. Evidence of any secondary glaucoma

3. Pigmentary dispersion
4. Pseudoexfoliation
5. History of trauma
6. History of uveitis
7. Any type of corneal disease or preceding refractive surgery

Date of first enrolment

30/05/2015

Date of final enrolment

30/09/2015

Locations

Countries of recruitment

Italy

Study participating centre

San Giuseppe Moscati Hospital

Italy

83100

Study participating centre

University of Molise

Italy

86100

Sponsor information

Organisation

G. Moscati Hospital

Organisation

Dipartimento di Medicina e Scienze per la Salute, Università degli Studi del Molise

Organisation

Azienda Ospedaliera S.Giuseppe Moscati

ROR

https://ror.org/021jxzw96

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/11/2016 | | Yes | No |