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

**Submission date**
05/02/2016

**Recruitment status**
No longer recruiting

**Registration date**
12/02/2016

**Overall study status**
Completed

**Last Edited**
20/06/2016

**Condition category**
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 though the eye (aqueous outflow system) using a solution containing viscoelastric 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

### Contact name
Prof Ciro Costagliola

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

### Secondary study design
Case series

### Study setting(s)
Hospital

### Study type(s)
Diagnostic

### Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

### Secondary outcome measures
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

### Overall study start date
30/05/2015

### Completion date
30/11/2015

## Eligibility

### Key inclusion criteria
Adult patients affected by POAG undergoing canaloplasty

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
Ten patients

### 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

**Sponsor details**
Contrada Amoretta
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**Sponsor type**
Hospital/treatment centre

**Website**
http://www.aosgmoscati.av.it/

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

**Sponsor details**
Via F. De Sanctis, 1
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dipmedicina@unimol.it

**Sponsor type**
University/education

**Website**
http://dipmedicina.unimol.it/il-dipartimento/

**Organisation**
Azienda Ospedaliera S.Giuseppe Moscati

**Sponsor details**

**Sponsor type**
Not defined

**Website**

http://www.aosgmoscati.av.it/

**ROR**
https://ror.org/021jxzw96

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Publication and dissemination plan**

**Intention to publish date**
31/05/2016

**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 |