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

Submission date	Recruitment status	[_] Prospectively registered
05/02/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/02/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/06/2016	Eye Diseases	

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?
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Contact information

Type(s)
Public

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Additional identifiers

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