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Xen Gel Stent: efficacy, safety and filtering bleb analysis at one year

Submission date
26/02/2017

Recruitment status
No longer recruiting

Registration date
09/03/2017

Overall study status
Completed

Last Edited
12/07/2017

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
Primary open angle glaucoma is a condition where the fluid in the eye cannot drain properly, which increases the pressure inside the eye and puts pressure on the optic nerve, which connects the eye to the brain. This can lead to loss of vision. This study is testing the XEN Gel Stent, a new device for the surgical treatment of glaucoma. This device is a tiny tube that is implanted into the eye to reduce the pressure by allowing fluid to drain to a small reservoir (bleb) just under the eye surface. The aim of this study is to assess the effectiveness and safety of the XEN Gel Stent and to investigate the bleb both clinically and using hi-tech methods in order to see if any parameter could guide the surgeons in obtaining better results.

Who can participate?
Patients age 20-70 with primary open angle glaucoma who cannot get their intraocular (eye fluid) pressure sufficiently low on between one and four anti-glaucoma medications

What does the study involves?
All patients undergo implantation of the XEN Gel Stent. Patients who have cataracts also undergo cataract surgery at the same time. The bleb is assessed using a microscope and a scan of the eye at 1, 3, 6 and 12 months after the operation. Safety is assessed by recording any adverse events (side effects) and loss of vision.

What are the possible benefits and risks of participating?
The potential benefits are to be free of or to reduce the burden of taking anti-glaucoma drugs. The risks are minimal although little is known on the long-term effectiveness of the device.

Where is the study run from?
University of Torino (Italy)

When is the study starting and how long is it expected to run for?
January 2014 to August 2015

Who is funding the study?
University of Torino (Italy)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
1.0

Study information

Scientific Title
Xen Gel Stent implantation in patients affected by primary open angle glaucoma: safety, filtering bleb analysis, intraocular pressure and glaucoma medication use variations within one year

Study objectives
Xen Gel Stent is a new and promising minimally invasive glaucoma surgery that creates a filtering bleb in the subconjunctival space and attempts to avoid the major complications related to standard filtering surgery. Safety and efficacy outcomes at one year after stent implantation in primary open angle glaucoma patients (as a solo procedure or combined with cataract surgery) have been poorly reported till now. Moreover, a filtering bleb assessment using different techniques (i.e. OCT and in vivo confocal microscopy) has never been provided.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Ophthalmic Hospital Turin, January 2014, ref: MS-001

Study design
Prospective interventional non-randomised study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Primary open angle glaucoma, cataract

Interventions
Patients underwent implantation of the Xen Gel Stent (AqueSys Inc, Aliso Viejo, CA, USA), a minimally invasive glaucoma surgery device that creates a subconjunctival filtering bleb through an ab interno approach. In some cases (i.e. patients with concurrent age-related cataract) cataract surgery was performed at the same time. Biomicroscopy, in vivo confocal microscopy (IVCM) and anterior segment OCT (AS-OCT) were used to assess bleb morphology at 1, 3, 6 and 12 months postoperative. Safety was determined by the incidence of adverse events, loss of best corrected visual acuity (BCVA), Humphrey visual field, and endothelial cell count.

Intervention Type
Device

Primary outcome(s)
1. Intraocular pressure, measured using Goldmann applanation tonometry (GAT) at baseline, 1 day, 7 days, 1, 3, 6, 9 and 12 months
2. Visual acuity, measured with the standard ETDRS charts at baseline, 1 day, 7 days, 1, 3, 6, 9 and 12 months
3. Incidence of adverse events, measured using a pre-built questionnaire at baseline, 1 day, 7 days, 1, 3, 6, 9 and 12 months
4. Visual field, measured using Humphrey 24-2 at baseline and 12 months
5. Endothelial cell count, measured using Konan Cell Check XL at 1, 3, 6 and 12 months

Key secondary outcome(s))
Bleb morphology, assessed using AS OCT (RTVue-100, Optovue) and in vivo confocal microscopy (HRTII/Rostock Cornea Module) at baseline, 1, 3, 6 and 12 months

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Patients with a diagnosis of POAG with uncontrolled IOP (defined as ≥18 mm Hg and ≤33 mm Hg on between one and four anti-glaucoma medications)
2. A healthy and mobile superior bulbar conjunctiva
3. Age 20-70

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Previous corneal and glaucoma surgery
2. Diagnosis of glaucoma other than POAG
3. Corneal opacities
4. Ocular diseases other than glaucoma

Date of first enrolment
12/06/2014

Date of final enrolment
20/12/2014

Locations

Countries of recruitment
Italy

Study participating centre
Ospedale Oftalmico
Dipartimento di Scienze Chirurgiche - Clinica Oculistica
V. Juvarra 19
Turin
Italy
10122

Sponsor information

Organisation
University of Torino

ROR

https://ror.org/048tbm396

Funder(s)

Funder type
University/education

Funder Name
University of Torino

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be included in the subsequent results publication

IPD sharing plan summary
Other