

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

<b>Submission date</b> 26/02/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/07/2017	<b>Condition category</b> 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

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?

Dr Antonio Fea  
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## Contact information

### Type(s)

Public

### Contact name

Dr Antonio Fea

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

No participant information sheet available

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/01/2014

**Completion date**

31/08/2015

## **Eligibility**

**Key inclusion criteria**

1. Patients with a diagnosis of POAG with uncontrolled IOP (defined as  $\geq 18$  mm Hg and  $\leq 33$  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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

11

**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

**Sponsor details**  
Eye Clinic  
Via Juvarra 19  
Torino  
Italy  
10100

**Sponsor type**  
University/education

**ROR**  
<https://ror.org/048tbm396>

## **Funder(s)**

**Funder type**  
University/education

**Funder Name**  
University of Torino

## **Results and Publications**

**Publication and dissemination plan**  
Planned publication in a peer reviewed journal

**Intention to publish date**  
09/03/2018

### **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