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# Efficacy of subconjunctival bevacizumab injections before and after surgical excision in preventing pterygium recurrence

**Submission date**
15/04/2017

**Recruitment status**
No longer recruiting

**Registration date**
18/04/2017

**Overall study status**
Completed

**Last Edited**
22/06/2017

**Condition category**
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
A pterygium is a wing-shaped growth of tissue across the cornea (the clear window at the front of the eye). It is caused by ultraviolet-light exposure, low humidity, and dust. Symptoms include persistent redness from smoke, inflammation, foreign body sensation, tearing, dry and itchy eyes. In advanced cases it can affect vision. There is a lack of agreement about the best treatment for pterygia. If the pterygium grows it is best to have it surgically removed. The main challenge to successful surgical removal is that the pterygium could come back again (recurrence). Many surgical techniques have been used, though none is universally accepted. The high recurrence rates associated with surgery continue to be a problem, and so additional medical treatments have been used, such as injection of the drug mytomicin C during surgery. Studies have shown that recurrence rates have dropped considerably with the addition of these treatments, but they are not without their own complications. Alternative and promising drugs have recently emerged, such as bevacizumab. Bevacizumab injections have been shown to be well tolerated in previous studies, but to date there is still a lack of consensus about the method of administration and dose needed in order to effectively reduce pterygium recurrence. The aim of this study is to assess the effectiveness and safety of injections of Bevacizumab, performed before and after surgery, at preventing pterygium recurrence.

Who can participate?
Patients over the age of 18 who have pterygium in one or both eyes

What does the study involve?
Participants are randomly allocated into two groups. Participants in the study group receive eye injections of bevacizumab 7 days before and 15 days after surgery. Participants in the control group do not receive bevacizumab and are treated with surgery alone. In case of pterygium in both eyes, the surgery is performed on one eye at a time. All participants receive a complete eye evaluation before the surgery. After the surgery, participants are asked to attend to follow-up visits after 1 day, 7 days, 1 month, 3 and 6 months and to follow the prescribed treatment (eyedrops, to prevent infection, for 15 days following the surgery). Recurrence rates are assessed at 1 day, 7 days, 1 month, 3 and 6 months after surgery.

What are the possible benefits and risks of participating?
Participants may experience a reduction of symptoms related to pterygium and, in some cases, an improvement in vision. There is a risk of complications due to the surgery (which, although rare, can be severe, such as corneal opacities/scarring, astigmatism induction and eye surface infection, or less serious like conjunctival haemorrhage [bleeding]) with the risk of loss of vision and eye surface discomfort. Recurrence of pterygium is still possible after surgery with the need for further treatment.

Where is the study run from?
S. Luigi University Hospital of Orbassano, University of Turin (Italy)

When is the study starting and how long is it expected to run for?
September 2015 to October 2016

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

Who is the main contact?
Prof. Raffaele Nuzzi

# Contact information

### Type(s)
Scientific

### Contact name
Prof Raffaele Nuzzi

### ORCID ID
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
07/15

# Study information

### Scientific Title
Evaluating postoperative pterygium recurrence rate modifications in patients receiving subconjunctival bevacizumab injections before and after surgical excision with bare sclera technique

### Study objectives
The aim of this study is to evaluate the efficacy of subconjunctival bevacizumab injections, before and after surgical excision with bare sclera technique, in preventing postoperative pterygium recurrence.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Internal Pharmaceutical Board of San Luigi Gonzaga University Hospital University of Turin, 26/11 /2015, ref: 7/2015

### Study design
Single-centre randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

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

### Health condition(s) or problem(s) studied
Pterygium

### Interventions
Participants will be randomized to one of the following groups:

Study group: Subconjunctival injection of Bevacizumab (2.5 mg/0.1 ml) followed by pterygium surgical excision with bare sclera technique after 7 days. 15 days after surgery all patients will receive a second subconjunctival Bevacizumab injection. The surgical technique is performed as described below:
1. Subconjunctival anesthetic (lidocaine 2%) injection in the area adjacent to the pterygium (5 mm from limbus)

2. Excision of the pterygium, starting from its head, followed by pterygium body removal
3. Exposition of a triangular-shaped bare scleral bed of little dimensions (with the base at the level of the limbus and margins of 1 mm each)
4. Conjunctival suture with vicryl 7-0 at the end of the procedure

Control group: Surgical excision of pterygium with the same technique performed in the study group

In case of bilateral pterygium, the procedure will be performed one eye at a time. All participants will receive a complete eye evaluation before being enrolled for surgery. After the procedure, patients are asked to attend to follow-up visits at 1 day, 7 days, 1 month, 3 and 6 months and to follow the prescribed therapy (eyedrops, to prevent infection, for 15 days following the procedure). Recurrence rate will be evaluated at 1 day, 7 days, 1 month, 3 and 6 months after surgery.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
Recurrence of pterygium (defined by growth of fibrovascular tissue extending more than 1 mm across the limbus), assessed by ophthalmological examination during follow-up visits at 1 week, 1 month, 3 and 6 months after the second subconjunctival injection (for the study group) or after surgery (for the control group).

### Secondary outcome measures
1. Grading of pterygium vascularization (according to the scheme proposed by Tan et al., Arch Ophthalmol 1997), assessed by ophthalmological examination during follow-up visits at 1 day, 1 month, 3 and 6 months after the second subconjunctival injection (for the study group) or after surgery (for the control group)
2. Pterygium dimensions, assessed by comparison of ocular anterior segment photographs captured 1 week before treatment with pictures captured at 1 week, 1 month 3 and 6 months follow-up visits

### Overall study start date
01/09/2015

### Completion date
20/10/2016

## Eligibility

### Key inclusion criteria
1. Aged over 18 years
2. Pterygium in one/both eye(s) extending more than 1 mm across the limbus

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
80 (40 patients per arm)

### Key exclusion criteria
1. Pregnancy
2. Ocular surface disease or infection
3. Autoimmune disorders
4. Previous limbal or corneal surgery

### Date of first enrolment
01/12/2015

### Date of final enrolment
31/05/2016

## Locations

### Countries of recruitment
Italy

### Study participating centre
**A.O.U. S. Luigi Gonzaga di Orbassano - University of Turin**
Regione Gonzole, 10
Orbassano
Italy
10043

## Sponsor information

### Organisation
S. Luigi Gonzaga University Hospital

### Sponsor details
Opthalmology section
AOU S. Luigi Gonzaga
Regione Gonzole, 10
Orbassano
Italy
10043

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/04nzv4p86

# Funder(s)

**Funder type**
University/education

**Funder Name**
Università degli Studi di Torino

**Alternative Name(s)**
University of Turin in Italy, University of Turin, Italy, Università di Torino, , University of Turin, UNITO

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
Italy

# Results and Publications

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

**Intention to publish date**
01/05/2017

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are intended to be available upon reasonable request forwarded to the Institute of Ophthalmology of University of Turin (segreteria.oculistica@unito.it)

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|

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|---|---|---|---|---|
| Results article | results | 01/01/2017 | Yes | No |