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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
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Protocol serial number
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

Primary study design
Interventional

Study design
Single-centre randomised controlled trial

Study type(s)
Treatment

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(s)
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).

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
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10043

Sponsor information

Organisation
S. Luigi Gonzaga University Hospital

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

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?
Results article	results	01/01/2017		Yes	No