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Comparison of hyperdry amniotic membrane transplantation and conjunctival autografting for primary pterygium

Submission date
03/04/2018

Recruitment status
No longer recruiting

Registration date
03/05/2018

Overall study status
Completed

Last Edited
23/11/2020

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 pinkish, triangular tissue growth on the cornea (the clear front covering of the eye). Surgical removal is considered the conventional definitive treatment of pterygium. The major problem associated with pterygium surgery is recurrence (regrowth of the pterygium), but none of the techniques have achieved complete success in completely preventing recurrence. The mainstay techniques presently in use include bare sclera excision followed by covering the defect with graft tissue such as a conjunctival autograft and amniotic membrane (AM). Currently, conjunctival autografting is the most commonly used technique with a lower recurrence rate and fewer complications despite the requirement for more technically demanding surgical skills and experience; it is more time-consuming to perform. Furthermore, it is not feasible to cover large defects created in large pterygia. Hyperdry (HD)-AM was developed as a new surgical patch. It is a new type of AM that is expanded on a nitrocellulose filter paper with epithelial sheet facing upward and cut into all kinds of squares, vacuum packed, and stored safely at room temperature. Recently, HD-AM has been used as a new tool for the management of many eye surface diseases, including corneal perforations and bleb leaks. The aim of this study is to find out whether HD-AM transplantation for patients with pterygium is an effective approach owing to a lower recurrence rate compared with conjunctival autografting .

Who can participate?
Patients with primary pterygium at least 2 mm onto the cornea or causing extreme irritation

What does the study involve?
Participants are randomly allocated to undergo either hyperdry amniotic membrane transplantation or conjunctival autografting for pterygium removal. After the operation, all participants use fluorometholone and tobramycin (Alcon) eye drops four times daily. The drops are gradually tapered back within one month. Sutures are removed after one week. The participants are examined on the first day after the operation, followed by the first week and then 1, 3, 6 and 12 months later. The minimum follow-up time is 6 months. The recurrence rate of pterygium after surgery is measured.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The Second Hospital of Jilin University (China)

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

Who is funding the study?
Jilin Education Department “Thirteen-Five” Science and Technology research (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016473

Study information

Scientific Title
Comparison of hyperdry amniotic membrane transplantation and conjunctival autografting for primary pterygium

Study objectives

HD-AM transplantation may be a superior treatment in primary pterygium owing to lower recurrence rate, shorter surgical times, and no major complications other than conjunctival autografting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Second Hospital of Jilin University, 28/2/2015, ref: [2015] No. 063

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Primary pterygium

Interventions
One hundred and forty-one eyes from 130 patients with primary pterygium were enrolled in this study. In all cases, the size of the pterygium was at least 2 mm onto the cornea or causing extreme irritation. Most of the pterygium was translucent, and the episcleral vessels underneath the body of the pterygium could be identified, as previously reported by Tan . Exclusion criteria included recurrent pterygium, dry eye, infection and inflammation of ocular area, glaucoma, and previous ocular surgery in the study eye. Patients were randomized into the hyperdry amniotic membrane transplantation or conjunctival autografting groups (HD-AM and CG groups, respectively) for pterygium excision. Informed consent for the surgery was signed by all patients. Patients with a <6-month follow-up period were excluded.

Surgical methods
Pterygium excision: All surgical procedures were performed by the same surgeon using an operating microscope (Zeiss, Germany). After injection of 2% lidocaine hydrochloride containing 1:10000 adrenaline (epinephrine) into the body of the pterygium, the conjunctival sac was irrigated with gentamicin, and the lid speculum was inserted. The head was separated and removed from the cornea by blunt dissection. Residual tissue over the corneal defect area was shaved with toothed forceps. Subconjunctival fibrous tissue under the pterygium was removed as much as possible avoiding damage to the underlying muscle sheath. A rectangular area of bare sclera was created to which the graft could be directly attached.

Hyperdry amniotic membrane transplantation:The hospital ethics committee approved the use of HD-AM in pterygium surgery (2015 No. 063) . After the preserved biological amniotic membrane (Jiangxi Ruiji BOI-Engineering Technology Co. Ltd.) was rinsed in physiological saline for 15 min (Fig. 1), it was cut into an appropriate size with scissors, peeled from the filter paper, and placed over the bare sclera area with epithelial basement membrane side facing up. The free edge of the HD-AM was sutured through the episcleral tissue to the edge of conjunctiva along the bare sclera border with 10-0 nylon sutures interrupted and was tightly pressed centrally to securely attach it to the bare sclera. The membrane was placed over the corneal lesion.

Conjunctival autograft transplantation: A conjunctival free graft of similar size was obtained from the superotemporal bulbar conjunctiva by splitting at the anatomic limbus. Careful excision was given to obtain a thin, tenon-free conjunctival graft. The limbal side of the autograft was sutured to the limbal side of the bare scleral bed by separate 10/0 nylon sutures. The donor site was later closed with a continuous suture of 10-0 nylon sutures.

Post-operation and Follow-up: Postoperatively, all the patients received 0.1% fluorometholone (Santen, Osaka, Japan) and tobramycin (Alcon) drops four times daily. The drops were gradually tapered back within one month. Sutures were removed after one week. The patients were examined on the first postoperative day, followed by the first week and then one, three, six, and 12 months postoperatively. The minimum follow-up time was six months. The recurrence rate of pterygium after surgery was used as the primary outcome in this study. Recurrence was defined as the regrowth of the fibrovascular proliferation tissue invading the cornea again. Other complications such as pyogenic granuloma, inclusion cyst, or scleral thinning were recorded.

Randomisation:

Patients were randomized into the hyperdry amniotic membrane transplantation or conjunctival autografting groups (HD-AM and CG groups,respectively) for pterygium excision by computerized randomization.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Recurrence defined as the regrowth of the fibrovascular proliferation tissue invading the cornea again, checked at first week and then 1, 3, 6 and 12 months postoperatively

Secondary outcome measures
1. Visual acuity is measured using a snellen chart at preoperative and postoperative day, first week and then 1, 3, 6, and 12 months postoperatively
2. Intraocular pressure (IOP) measured using a non-contact tonometer at preoperative and postoperative day, first week and then 1, 3, 6, and 12 months postoperatively
3. The size of the pterygium is measured using slit lamp at preoperative day
4. Complications measured using slit lamp at first week and then 1, 3, 6, and 12 months postoperatively
5. Pain is recorded at postoperative day, first week and then 1, 3, 6, and 12 months postoperatively
6. Surgical times, recorded during the surgery

Overall study start date
01/03/2015

Completion date
01/03/2016

Eligibility

Key inclusion criteria
1.The size of the pterygium is at least 2 mm onto the cornea or causing extreme irritation.
2. Most of the pterygium is translucent, and the episcleral vessels underneath the body of the pterygium can be identified
3. Patients 30-80 years old

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
140

Total final enrolment
130

Key exclusion criteria
1. Recurrent pterygium
2. Dry eye
3. Infection and inflammation of ocular area
4. Glaucoma
5. Previous ocular surgery in the study eye
6. Patients with a <6-month follow-up period

Date of first enrolment
08/03/2015

Date of final enrolment
01/02/2016

Locations

Countries of recruitment
China

Study participating centre
The Second Hospital of Jilin University
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Sponsor information

Organisation
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Sponsor type
Government

ROR
https://ror.org/03x6hbh34

Funder(s)

Funder type
University/education

Funder Name
The Plan of Jilin Education Department “Thirteen-Five” Science and Technology research [2016] No.473

Results and Publications

Publication and dissemination plan
As of 29/04/2018, the manuscript was under minor revision with BMC Ophthalmology.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Xin Pan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/05/2018	23/11/2020	Yes	No