Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of two techniques of pterygium surgery, Rotational autograft from pterygium tissue versus free conjunctival graft in patients suufering from pterigyum: a clinical trial

Protocol summary

Summary

The aim of this study was to evaluate the rate of recurrence in two methods of the pterygium surgery. This was a randomized, single blind, single-centered study. 45 patients suffering from pterygium referred to the Shiraz Khalili Hospital entered into intervention and control groups respectively. The inclusion criteria were: the presence of primary pterygium with surgical indications and age younger than 55. The exclusion criteria of the study include: the pterygiums being suspicious of conjunctival intraepithelial neoplasia, the presence of symblepharon, recrudescent pterygiums, double head pterygium, pseudopterygia, having any history of eye disease. In both groups, pterygium was treated by surgery in combination with interaoperative mitomycin C. In the intervention group pterygium tissue and in the control group supra temporal conjunctiva was used as the transplantation tissue. Patients were evaluated for recurrence and other complications such as hyperemia and appearance of the eye after surgery (main outcomes).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092119581N2**
Registration date: **2017-11-04, 1396/08/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-11-04, 1396/08/13

Registrant information

Name

Shahram Bamdad

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

shahrambamdad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2014-01-13, 1392/10/23

Expected recruitment end date

2014-07-17, 1393/04/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two techniques of pterygium surgery, Rotational autograft from pterygium tissue versus free conjunctival graft in patients suufering from pterigyum: a clinical trial

Public title

Comparison of two techniques of pterygium surgery: graft from pterygium tissue versus free conjunctival graft

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria were: the presence of primary

pterygium (temporal or nasal), having surgical indications (vision deterioration as a result of the involvement of visual axis and inducing irregular astigmatism, chronic eye irritation, recrudescent inflammation, limitation of eye movement, cosmetic problems, and more than 2 mm growth on the cornea), and the patient who were younger than 55. Primary pterygium is defined as having no history of pterygium surgery for the target eye. Exclusion criteria: the pterygiums being suspicious of conjunctival intraepithelial neoplasia; the presence of symblepharon; recrudescent pterygiums; double head pterygium; pseudopterygia; having a history of eye trauma and corneal scar.

Age
From **19 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
according to the visit patients with the odd numbers were puted in the intervention group and with the number of couples in the control group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz, Iran

City
Shiraz

Postal code
7134814336

Approval date
2015-08-05, 1394/05/14

Ethics committee reference number
IR.SUMS.med.REC.1394.43

Health conditions studied

1

Description of health condition studied
pterygium

ICD-10 code
H11.0

ICD-10 code description
Pterygium

Primary outcomes

1

Description
recurrence

Timepoint
6 Months after the intervention.

Method of measurement
Slit lamp

Secondary outcomes

1

Description
graft injection

Timepoint
6 Months after the intervention.

Method of measurement
with slit lamp

2

Description
cosmesis

Timepoint
6 Months after the intervention.

Method of measurement
with slit lamp

Intervention groups

1

Description
Intervention group: Pterygium surgery by using pteygium as transplanted tissue. In this method after pterygium removal, the fibrovascular tssue was removed from the pterygium and with 180 degree rotation was sutured to place. Except for the surgical procedure, all follow-up procedures were the same in two methods.

Category
Treatment - Surgery

2

Description
control group: pterygium surgery with free graft, In this method, after the removal of the pterygium, the supra temporal conjunctiva was used as graft. the patients

were followed for 6 months.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Doctor Shahram Bamdad

Street address

Khalili Hospital, Khalili Street, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Doctor Sayed Basir Hashemi

Street address

The headquarters of the Palestinian street Shyrazrvbrvy University of Medical Sciences, Zand Street, Shiraz,

City

Shiraz

Grant name

پایان نامه دانشجویی

Grant code / Reference number

93-01-01-8901

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Doctor Shahram Bamdad

Position

Assistant Professor, Department of Ophthalmology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Fellowship of anterior segment and and ocular surface disease

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty