

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two techniques of pterygium surgery, Rotational autograft from pterygium tissue versus free conjunctival graft in patients suffering from pterygium: 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, recrudescant pterygiums, double head pterygium, pseudopterygia, having any history of eye disease. In both groups, pterygium was treated by surgery in combination with intraoperative 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 suffering from pterygium: 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, recrudescence 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; recrudescence 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 put 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 pterygium as transplanted tissue. In this method after pterygium removal, the fibrovascular tissue 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
Shiraz 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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Doctor Shahram Bamdad

Position

Fellowship of anterior segment and and ocular
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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