

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of conjunctival autografts and amniotic membrane grafts for treatment of pterygium.

Protocol summary

Summary

Aim: The purpose of the study is to determine whether amniotic membrane can be used as an alternative to conjunctival autograft after pterygium excision. Design: Randomized clinical trial. Methods: seventy eyes with either primary or recurrent pterygium are included in this study. All eyes are randomized to undergo conjunctival autograft or amniotic membrane transplantation after pterygium excision by a single surgeon. Twenty seven eyes with primary and 8 eyes with recurrent pterygium will be treated with conjunctival autograft, and 26 eyes with primary and 9 eyes with recurrent pterygium will be treated with amniotic membrane transplantation. Patients are followed up at one week, one month and three months after operation. The main outcome measurement is recurrence rate after surgery. The patients with inadequate follow up are excluded from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100114697N1**

Registration date: **2013-10-05, 1392/07/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-10-05, 1392/07/13

Registrant information

Name

Mehdi Alizadeh

Name of organization / entity

Hamadan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0572

Email address

m.alizadeh@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Science

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of conjunctival autografts and amniotic membrane grafts for treatment of pterygium.

Public title

Comparison of conjunctival autografts and amniotic membrane grafts for treatment of pterygium.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with primary or recurrent pterygium. Exclusion criteria: Patients with inadequate follow up after surgery.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Block Randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Science

Street address

Shahid Fahmideh Street, Hamadan

City

Hamadan

Postal code

6541844886

Approval date

2013-09-10, 1392/06/19

Ethics committee reference number

1688/9/35/16/د/پ

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

One week, one month and three months post op.

Method of measurement

Slit lamp

2

Description

Inflammation

Timepoint

One week, one month and three months post op.

Method of measurement

Slit lamp

Secondary outcomes

1

Description

Refraction

Timepoint

Pre operation and one week, one month and three months post op.

Method of measurement

Refractometer

Intervention groups

1

Description

Intervention: Amniotic Membrane Transplantation (Amniotic membrane is separated from its carrier paper under a microscope and is expanded on denuded area in order to cover the bare sclera.)

Category

Treatment - Surgery

2

Description

Control: Conjunctival Autograft Transplantation (Conjunctival graft is removed from the superior region of the sick eye and is expanded on denuded area in order to cover the bare sclera.)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital of Hamadan

Full name of responsible person

Mehdi Alizadeh-Nasrin Mohebi

Street address

Mirzadeh Eshghi Street, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamadan University of
Medical Science

Full name of responsible person

Yosef Alikhani

Street address

Shahid Fahmideh Street, Hamadan

City

Hamadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Hamadan University of
Medical Science

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**

Hamadan University of Medical Science

Full name of responsible person

Mehdi Alizadeh

Position

Assistant professor

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Mehdi Alizadeh

Position

Ophtalmologist

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Web page address**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