

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The role of umbilical cord serum therapy on improvement of corneal epithelial defect following diabetic vitrectomy

Protocol summary

Summary

Eighty diabetic patients who are underwent vitrectomy and have no history of Eye herpes infection, Refractive surgery, Autoimmune disease and Immune deficiency will be randomized into two groups to evaluate the role of umbilical cord serum therapy on improvement of corneal epithelial defect following diabetic vitrectomy. Both groups will take the conventional medication including Chloramphenicol, Betamethasone and Cycloplegic eye drops and the case group will take further umbilical cord serum eye drop in the operated eye. The corneal epithelial defect will be measured by slit lamp after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903241180N15**

Registration date: **2010-06-14, 1389/03/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-14, 1389/03/24

Registrant information

Name

pooya rostami

Name of organization / entity

Ophthalmic Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 5952

Email address

labbafi@hotmail.com

Recruitment status

Recruitment complete

Funding source

Ophthalmic Research Center

Expected recruitment start date

2009-12-28, 1388/10/07

Expected recruitment end date

2010-02-04, 1388/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of umbilical cord serum therapy on improvement of corneal epithelial defect following diabetic vitrectomy

Public title

The role of umbilical cord serum therapy on corneal epithelial defect

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diabetic patients with corneal epithelial defect following diabetic vitrectomy at labbafinejad hospital. Exclusion criteria: 1) Any history of Eye herpes infection, Refractive surgery, Autoimmune disease, Immune deficiency; 2) patients with one eye 3) use of any eye drops except Chloramphenicol, Betamethasone, Cycloplegic and contact lens for corneal epithelial defect.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ophthalmic Research Center

Street address

No 23, Pasdaran Ave, 9th Boostan, Ophthalmic Research Center

City

Tehran

Postal code

166666

Approval date

2010-03-17, 1388/12/26

Ethics committee reference number

7699 ت ج

Health conditions studied

1

Description of health condition studied

corneal epithelial defect

ICD-10 code

H18.9

ICD-10 code description

Disorder of cornea, unspecified

Primary outcomes

1

Description

measurement of corneal epithelial defect

Timepoint

days 3,5,7,12

Method of measurement

slit lamp

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: chloramphenicol and betamethasone eye drops every 6 hours, cycloplegic (homatropine) eye drop every 8 hours plus umbilical cord serum eye drop 20% every 4 hours

Category

Treatment - Drugs

2

Description

Control: chloramphenicol and betamethasone eye drops every 6 hours, cycloplegic (homatropine) eye drop every 8 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinejad Hospital

Full name of responsible person

Dr Siamak Moradian

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ophthalmic Research Center

Full name of responsible person

Ali-asghar Aghdai

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No 23, Pasdaran Ave, 9th Boostan, Ophthalmic Research Center

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ophthalmic Research Center

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
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Full name of responsible person
Dr Amir Faramarzi
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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