Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Safety and efficacy of fibrin glue prepared from umbilical cord blood for attaching Conjunctival graft after pterygium excision

Protocol summary

Summary

Aim: The purpose of this study is to compare the fibrin glue prepared from Umbilical Cord Blood (UCB) Royan Institute, Tehran, Iran with a standard glue in pterygium excision surgery. Design: Randomized Clinical Trial Setting: Baqiyatallah Hospital, Ophthalmology Department, Tehran, Iran Major inclusion criteria: Patients who are suffering from pterygium associated with reduced visual acuity due to the proximity of pterygium to the visual axis; irregular astigmatism; and considerable ocular discomforts which are not responsive to the standard cares. Exclusion criteria: those who are suspected to ocular surface malignancies and/or keratoconjunctivitis; recurrent pterygium; systemic diseases (eg. diabetes, hypertension). Intervention: in the case group following pterygium excision surgery, conjunctival graft will be attached by umbilical cord blood fibrin glue, while in the control group, attachment will be accomplished by standard fibrin glue. Outcome measures: Complete loss of graft, partial graft dehiscence, graft hyperemia, subconjunctival hemorrhage, recurrence rate, post-operative pain and other ocular surface side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021132503N1**
Registration date: **2017-06-26, 1396/04/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

Name

Hossein Aghamollaei

Name of organization / entity

Baqiyatallah University of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-03-28, 1396/01/08

Expected recruitment end date

2017-08-31, 1396/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of fibrin glue prepared from umbilical cord blood for attaching Conjunctival graft after pterygium excision

Public title

Safety and efficacy of fibrin glue prepared from umbilical cord blood in pterygium excision

Purpose

Treatment

Inclusion/Exclusion criteria

Patients who are suffering from pterygium associated with reduced visual acuity due to the proximity of pterygium to the visual axis, irregular astigmatism, and considerable ocular discomforts which are not responsive

to the standard cares will be included in this study, whereas those who are suspected to ocular surface malignancies and/or keratoconjunctivitis, recurrent pterygium, and other general diseases (eg. Diabetes, hypertension) will be excluded.

Age
From **20 years** old to **75 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization will be attained by using of random number tables.

Secondary Ids

1

Registry name
None

Secondary trial Id
None

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Baqiyatallah University of Medical sciences

Street address
Baqiyatallah University of Medical sciences

City
Tehran

Postal code

Approval date
2014-08-20, 1393/05/29

Ethics committee reference number
IR.BMSU.REC.1392.82

Health conditions studied

1

Description of health condition studied
Pterygium

ICD-10 code
H11.0

ICD-10 code description
Conjunctival degenerations and deposits

Primary outcomes

1

Description
Subconjunctival hemorrhage

Timepoint
1,3 and 5 day and 1 and 3 months after surgery

Method of measurement
Mild:less than 1/3of graft, Moderate: from 1/3 to 2/3 of graft and sever: more than 2/3 of graft.

2

Description
Hyperemia

Timepoint
1,3 and 5 day and 1 and 3 months after surgery.

Method of measurement
Grade 0 – Absent (in case of normal vessels), Grade I – Mild (low vascular hyperemia), Grade II – Moderate (disseminated hyperemia), and Grade III – severe (hyperemia with disseminated vascular dilatation

3

Description
complete loss of graft

Timepoint
1,3 and 5 day and 1 and 3 months after surgery.

Method of measurement
observation

4

Description
partial graft dehiscence

Timepoint
1,3 and 5 day and 1 and 3 months after surgery.

Method of measurement
observation

5

Description
Recurrence rate

Timepoint
1 and 3 month after surgery

Method of measurement
observation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The UCB-fibrin glue will be formulated in Royan Institute, Tehran, Iran. This is a prepared drop from the umbilical cord blood plasma of healthy mothers under sterile condition. In operation room, two drops of UCB-thrombin and one drop of UCB-Fibrinogen will be mixed and the resulting mixture will be put beyond the graft on its posterior position in a way that its limbus will be directed towards the limbus of the lesion

Category
Treatment - Surgery

2

Description
Control group: In control group, by using standard fibrin glue (Beriplast P, Germany), under company protocol, two drops of thrombin and one drop of fibrinogen will be used under the posterior surface of the graft in a way that its limbus will be directed towards the limbus of the lesion.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiyatallah hospital

Full name of responsible person

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
investigator

Full name of responsible person
investigator

Street address
Baqiyatallah Hospital, Mollasadra street

City
Tehran

Grant name
-

Grant code / Reference number
-

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

Title of funding source
investigator

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
Royan Institute for Stem Cell Biology and Technology

Full name of responsible person
Marzieh Ebrahimi

Position
associate Profossor

Other areas of specialty/work

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Royan Institute for Stem Cell Biology and Technology, , Hafez street, Hemmat highway

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Hossein Aghamollaei

Position

Ph.D

Other areas of specialty/work

Street address

City

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Postal code

Phone

00

Fax

Email

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