

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

Iran (Islamic Republic of)

Phone

+98 21 8248 2260

Email address

abrcl@bmsu.ac.ir

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

Street address

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

City

Tehran

Postal code

Phone

+98 989123448359

Fax

Email

marzieh.ebrahimi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Baqiyatallah university of Medical Sciences

Full name of responsible person

Khosrow Jadidi

Position

associate Profossor

Other areas of specialty/work

Street address

Department of Ophthalmology, Baqiyatallah
university of Medical Sciences, Molasadra street

City

tehran

Postal code

Phone

+98 21 8248 2260

Fax

Email

Kh.jadidi@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Applied Biotechnology research Center, Baqiyatallah
University of Medical sciences

Full name of responsible person

Hossein Aghamollaei

Position

Ph.D

Other areas of specialty/work**Street address****City**

Tehran

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