Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Pterygium surgery by using autologous conjunctival cells transplantation implanted on human amniotic membrane

Protocol summary

Study aim
Pterygium surgery by using autologous conjunctival cells transplantation implanted on human amniotic membrane

Design
Clinical trial without control group with sample size of 30 patients

Settings and conduct
We get a 1&2 mm from inferior fornix two weeks before surgery. After detachment and removal of the tenon capsule, the epithelial layer will be referred to the culture laboratory. After chopping the sample, we will put the segments on the amniotic membrane (on the basement membrane) and located in serumless keratinocyte growth culture media. After expansion, the implant will be kept secured in a place of bare sclera by nylon 10-0 sutures.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the presence of primary pterygium. Exclusion Criteria: Recurrent pterygium; history of pterygium surgery.

Intervention groups
Patients with primary pterygium who are candidates for doing pterygium surgery underwent getting a sample of conjunctiva from inferior fornix. This sample will be sent to a laboratory for cellular expansion. If the cells grow efficiently after two weeks, we will have transplanted them after doing pterygium surgery. After transplantation, epithelialization of the conjunctiva and recurrence of pterygium will be evaluated in different follow-up times.

Main outcome variables
Expression of the epithelium; Evaluation of the amount of collagen; Evaluation of the epithelialization; Evaluation of the recurrence; Evaluation of the inflammation.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210513051283N1**
Registration date: **2021-08-15, 1400/05/24**
Registration timing: **prospective**

Last update: **2021-08-15, 1400/05/24**
Update count: **0**

Registration date
2021-08-15, 1400/05/24

Registrant information

Name
Hossein Aghaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6650 9162

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aghaei.h@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
2021-09-23, 1400/07/01

Actual recruitment end date
2022-03-20, 1400/12/29

Trial completion date
2022-03-20, 1400/12/29

Scientific title
Pterygium surgery by using autologous conjunctival cells transplantation implanted on human amniotic membrane

Public title

Evaluation of the expanded conjunctiva in pterygium surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

presence the primary pterygium

Exclusion criteria:

Dissatisfaction patients

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway near to Milad Tower Iran University of medical Sciences

City

Tehran

Province

Tehran

Postal code

99-2-86-19057

Approval date

2021-04-20, 1400/01/31

Ethics committee reference number

IR.IUMS.REC.1400.118

Health conditions studied

1

Description of health condition studied

primary pterygium-

ICD-10 code

H11.0

ICD-10 code description

Pterygium of eye

Primary outcomes

1

Description

Evaluation of re-epithelialization of cultivated tissue

Timepoint

Before conjunctival transplantation

Method of measurement

Hematoxilin-eosin staining

2

Description

Evaluation of collagenesis

Timepoint

Before conjunctival transplantation

Method of measurement

Trichrome-mason staining

3

Description

Evaluation of re-epithelialization and collagenesis of cultivated tissue

Timepoint

Before conjunctival transplantation

Method of measurement

Expression of integrin B 1,MUC4,CX43,Oct4,p63,CK19,CK13,CK12,CK3 by RT-PCR

4

Description

Healing process of transplanted conjunctiva

Timepoint

Day 1,3,7 and months 1,3,6,12

Method of measurement

Examination and Fluorescin staining

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We will get a sample of conjuctiva, 2x1 mm, from inferior fornix of the eye with pterygium two weeks before operation. After isolation the epithelium from tenon layer, the sample will be sent to laboratory. In laboratory this sample will be chopped and

implanted over amniotic membrane (epithelial side). Then, this complex will be put in an acellular culture media, keratonocyte growth media, that consists of 10 ng/ml human epidermal growth factor (Gibco) ،5 _g/ml insulin (Sigma) ،0.5 _g/ml hydrocortisone (Sigma) 30 _g/ml bovine pituitary extract (Sigma) ،50 _g/ml Gentamicin (Gibco) ،50 ng/ml Amphotericin B (Gibco). Calcium concentration is 15/0 Millimol in culture media. Adhesion and proliferation of cells will increase by increasing the calcium concentration to 9/0 Mm. The chopped sample and 500 micro- liters culture media will have cultured in an incubator of 37 centigrade temperature, 5/5 % Co2 and 95% humidity for one to two weeks. the culture media will change every two to three days and at each change cells will evaluate by microscope. we will use of more amount of culture media by adhesion the cells to amniotic membrane. We evaluate the cells based on rate of cells growth and adhesion to amniotic membrane every day. In addition, cells growth is visible by color change of culture media. After ending the cultivation and proliferation of cells on amniotic membrane, the complex will put up in a new culture media that consists of Dulbecco's Modified Eagle's Medium (DMEM) and Ham's F12 media (Gibco), supplemented with 2.5% fetal bovine serum (Hyclone, Logan, Utah), 10 ng/ml human epidermal growth factor, 5 _g/ml insulin, 0.4 _g/ml hydrocortisone, 8.4 ng/ml cholera toxin (Sigma), 50 _g/ml streptomycin (Gibco), and 50 IU/ml penicillin (Gibco) for three days.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rassoul Akram Hospital

Full name of responsible person

Hossein Aghaei

Street address

Niayesh Avenu, Satar Khan Street Rassoul Akram Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Aghaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Subspecialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable