Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Simultaneous effect of tacrolimus drops and PRP and its comparison with artificial tacrolimus drops in the treatment of chronic dry eye in patients referred to the hospital

Protocol summary

Study aim
Simultaneous effect of tacrolimus drops and PRP and its comparison with artificial tacrolimus drops in the treatment of chronic dry eye in patients referred to the hospital

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 18 patients. In order to randomize, the block randomization method will be used.

Settings and conduct
In this study, all patients with renal impairment who referred to Shafa Hospital will be enrolled. Patients will be randomly divided into 3 groups based on 6 blocks. The sample size for each study group is 6. A total of 18 patients will be examined. Patients, doctor and data analyzer will be blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients over 18 years, Corneal staining, Schirmer test is less than 5 mm in 5 minutes, BUT test is less than 5 seconds. Exclusion criteria: pregnancy, lactation, history of glaucoma and previous surgery or trauma, use of eye drops except for artificial tears, use of contact lenses.

Intervention groups
Intervention group 1: Patients receive only artificial tear drops Intervention group 2: Patients receive only tacrolimus drops Intervention group 3: Patients receive a combination of tacrolimus drops with PRP

Main outcome variables
BUT test; Corneal staining; Schirmer test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211011052725N1**
Registration date: **2021-12-24, 1400/10/03**
Registration timing: **prospective**

Last update: **2021-12-24, 1400/10/03**
Update count: **0**

Registration date
2021-12-24, 1400/10/03

Registrant information

Name
farzane barzegarpur

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3428 2227

Email address
barzegarf1368@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-10, 1400/10/20

Expected recruitment end date
2022-07-11, 1401/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Simultaneous effect of tacrolimus drops and PRP and its comparison with artificial tacrolimus drops in the treatment of chronic dry eye in patients referred to the

hospital

Public title
Effect of tacrolimus drops and PRP in the treatment of chronic dry eye

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients over 18 years Corneal staining Schirmer test is less than 5 mm in 5 minutes BUT test is less than 5 seconds.

Exclusion criteria:
Pregnancy Lactation Pregnancy, lactation, history of glaucoma and previous surgery and trauma Use of eye drops other than artificial tears, and use of contact lenses.

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **18**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into three groups. Randomization tool will be random sequence generation software that in addition to simple randomization, these random sequence generation software are able to generate random sequence by blocking method. In order to randomize, the block randomization method will be used. Block randomization is to make sure that exactly the same number of participants enter the study groups. The advantage of block randomization is that the balance of the number of participants in each group is guaranteed. For this purpose, 6 blocks will be formed and in each block, 2 people from intervention group 1, 2 people from intervention group 2 and 2 people in intervention group 3 will be placed. A total of 3 blocks will be considered to reach the sample size. For concealment, random allocation concealment will be used, which is the method used to execute a random sequence on the study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with a random sequence, in this method, each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the letter envelopes are glued and placed in a box, respectively. the door At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients will be unaware and blind to the type of drugs. In order to blind, the desired drops are provided to patients in similar packages and in coded form, and patients will not be aware of the content of their medication. Patients will be aware that they will be randomly assigned to one of three treatment groups, but will be unaware of which treatment will be provided in that group. The physician also knows that patients will be anesthetized in three different ways, but will not know which procedure will be performed for each patient. The data collection officer, analyst and outcome assessor will collect and analyze information based on groups 1, 2 and 3 and will not be aware of the type of treatment provided in the groups. They will be kept blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Shafa Educational and Medical Center, Kowsar Boulevard

City
Kerman

Province
Kerman

Postal code
7618751151

Approval date
2020-04-27, 1399/02/08

Ethics committee reference number
IR.KMU.REC.1399.075

Health conditions studied

1

Description of health condition studied
Dry eye syndrome

ICD-10 code
H04.12

ICD-10 code description
Dry eye syndrome

Primary outcomes

1

Description
BUT test (Fluorescein disappears from Fornix)
Timepoint
One week, one month and three months after starting treatment
Method of measurement
Clinical examination of the patient - per second

2

Description
Corneal staining
Timepoint
One week, one month and three months after starting treatment
Method of measurement
Clinical examination of the patient

3

Description
Schirmer test
Timepoint
One week, one month and three months after starting treatment
Method of measurement
Clinical examination of the patient - In millimeters per minute

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients receive only artificial tear drops. Patients will use one drop three times a day, each time at eight-hour intervals. 10 ml drops will be for a patient's dose of one month. This amount will be repeated for the second and third month.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients receive only tacrolimus drops. One mg of tacrolimus is dissolved in five mg of buffer phosphate and given to the patient in sterile eye drops. Patients will use one drop three times a day, each time at eight-hour intervals. 10 ml drops will be for a patient's dose of one month. This amount will be repeated for the second and third month.
Category
Treatment - Drugs

3

Description
Intervention group 3: Patients receive a combination of tacrolimus drops with PRP. One mg of tacrolimus is dissolved in 5 mg of buffer phosphate and after mixing with 5 ml of autologous PRP in sterile eye drops will be given to the patient. Patients will use one drop three times a day, each time at eight-hour intervals. 10 ml drops will be for a patient's dose of one month. This amount will be repeated for the second and third month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Educational and Medical Center
Full name of responsible person
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Sponsors / Funding sources

1

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Full name of responsible person
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shafahospital@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Farzaneh Barzegarpur
Position
resident
Latest degree
Medical doctor
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Ophthalmology
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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