Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative clinical evaluation of 0.05% Cyclosporine and 0.05% Nano - Tacrolimus eye drops for the treatment of dry eye

Protocol summary

Study aim

Comparative evaluation of the efficacy of Nano formulation of Tacrolimus and Cyclosporine eye drops in patients with dry eye

Design

A randomized clinical trial was conducted using table of random numbers, double-blind, and parallel group design with 24 patients with dry eye syndrome, followed up for one month.

Settings and conduct

On 24 patients with dry eye syndrome referred from the rheumatology clinic, Ocular Surface Disease Index (OSDI) questionnaire, Schirmer test, Tear film break up time test (TBUT)and Sm-tube and the slit lamp examination in Ophthalmology Clinic Vali Asr done. After confirming dry eye, the patient is given Nano-tacrolimus and cyclosporine drugs for use in each eye for one month and every two weeks they were followed-up for possible adverse side-effects . The ophthalmologist does not know which drug is used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with burning symptoms, foreign body sensation and dryness in both eyes,blurring of vision, photo phobia,and pain, abnormal Schirmer test, TBUT test,OSDI index and SM tube enrolled in the study. Exclusion criteria: pregnancy and lactation, patients with any structural disorder, any inflammation in the anterior chamber, glaucoma, previous eye surgery, recent use of topical or systemic antibiotics or anti-inflammatory drugs, contact lenses, corneal infections.

Intervention groups

Tacrolimus drops for one eye and Cyclosporine for other eyes twice a day for one month.

Main outcome variables

Measuring of schirmer test, SM-Tube,TBUT and OSDI

General information

Reason for update

1. Changing the scientific and public title due to more appropriateness and better observance of English writing 2. Changing the study phase to phase 3 because the previous phases have been done 3. Age change due to the ineffectiveness of age in the study 4. Changing the inclusion criteria because Sjogren is one of the causes of dry eye and patients other than Sjogren with dry eye were included in the study. 5. Changing the exclusion criteria due to duplication and incompleteness 6. Randomization change due to sample size change 7. Changing the sample size due to the lack of financial budget and sanctions on raw materials for drug production

Acronym

IRCT registration information

IRCT registration number: **IRCT20181006041253N1**
Registration date: **2019-01-08, 1397/10/18**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-14, 1400/03/24**
Update count: **1**

Registration date

2019-01-08, 1397/10/18

Registrant information

Name

Mozhgan Ahrary

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date
2019-01-21, 1397/11/01
Actual recruitment start date
2018-12-22, 1397/10/01
Actual recruitment end date
2019-01-21, 1397/11/01
Trial completion date
2019-01-21, 1397/11/01

Scientific title
Comparative clinical evaluation of 0.05% Cyclosporine and 0.05% Nano -Tacrolimus eye drops for the treatment of dry eye

Public title
Nano-Tacrolimus and Cyclosporine effect in dry eye
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
chronic symptoms of burning, foreign body sensation or itching in both eyes, blurring of vision, photo phobia,and pain daily need for artificial tears The ocular surface disease index (OSDI)≥23 tear film break-up time (TBUT) value of 10s or lower Strip Meniscometry test (SM tube) ≤ 10 mm Schirmer test value at 5 min of 10mm or lower
Exclusion criteria:
Sensitivity to tacrolimus Pregnancy or lactation Other systemic atopic diseases Previous eye surgery Any structural abnormalities (lid scarring, entropion, trichiasis, etc.) Any inflammation in the anterior chamber Glaucoma Use of other topical drugs, other than artificial tears Use of topical or systemic antibiotics or anti-inflammatory drugs before entering the study Contact lens punctual occlusion
Age
From **30 years** old to **78 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**
Actual sample size reached: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
We assigned patients a code from 1 to 12. Then we used a table of random numbers to select 12 numbers. For the 12 selected patients, the 0.05% Nano- Tacrolimus drug was used in the right eye and the 0.05% CsA drug was used in the left eye. On the other 12 patients, 0.05% Nano- Tacrolimus was used in the left eye and the 0.05% CsA drug was used in the right eye
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study,the ophthalmologist who performs the examination and evaluation of the patients and the person who performs the data analysis is unaware of which drug is used.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Birjand University of Medical Sciences
Street address
Ghaffari Street
City
Birjand
Province
South Khorasan
Postal code
9717853577
Approval date
2018-06-20, 1397/03/30
Ethics committee reference number
IR.BUMS.REC.1397.071

Health conditions studied

1

Description of health condition studied
Dry eye syndrome
ICD-10 code
H04.1
ICD-10 code description
Other disorders of lacrimal gland

Primary outcomes

1

Description
Foreign body sensation
Timepoint
Before intervention and one month after treatment
Method of measurement
Ocular Surface Disease Index (OSDI)

2

Description
Tear film break up time test (TBUT)
Timepoint
Before intervention and one month after treatment

Method of measurement
In seconds, with a timer and slit lamp

3

Description
Production of tears
Timepoint
Before intervention and one month after treatment
Method of measurement
Schirmer's test in millimeters

4

Description
Tear volume measurement (SM Tube)
Timepoint
Before intervention and one month after treatment
Method of measurement
The SM Tube strip is held in the lower lip for 5 seconds. After 5 seconds, the height of the absorbed tear of the blue column is measured.

5

Description
Light sensitivity
Timepoint
Before intervention and one month after treatment
Method of measurement
Ocular Surface Disease Index (OSDI)

6

Description
Blurred vision
Timepoint
Before intervention and one month after treatment
Method of measurement
Ocular Surface Disease Index (OSDI)

7

Description
Eye irritation
Timepoint
Before intervention and one month after treatment
Method of measurement
Ocular Surface Disease Index (OSDI)

Secondary outcomes

empty

Intervention groups

1

Description
International group 1: 0.05% nano formulation Tacrolimus drop produced at the Abu Reyhan Pharmacy Company for one eye twice a day, One drop use in the lower conjunctiva for one month.
Category
Treatment - Drugs

2

Description
International group 2: Cyclosporine drop Sinadarou Company uses a drop in the lower conjunctiva for one month twice a day for another eye.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Vali Asr Hospital
Full name of responsible person
Mozhgan Ahrary
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Sponsors / Funding sources

1

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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
Birjand 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Because of the publication of the article
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available