

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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 Ahrari

Name of organization / entity

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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

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Ghaffari Street

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South Khorasan

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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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

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Position

Medical Student

Latest degree

Medical doctor

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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