Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of artificial tear drops and baby shampoos as treatments of dry eye syndrome(DES), with and without the administration of simple eye ointment

Protocol summary

Summary

In this clinical trial study which is carried out to compare artificial tear drops and baby shampoos as treatments of dry eye syndrome, with and without the administration of simple eye ointment, patients with DES receipted at the ophthalmology clinic of Semnan Kowsar Hospital or at the concerning ophthalmologist's office, are evaluated by the inclusion criteria, before entering the study. The main inclusion criteria: Patients must be between 20 and 60 years old. Patients must be diagnosed with DES for first time. Patients with idiopathic DES, not secondary types.Disease progression must be staged as mild or moderate.No history of undergoing refractive errors surgeries, utilizing contact eye lens and any drugs associated to DES The main exclusion criteria:- Refusal to keep participating in the study.Intolerance to treatment Patients enter the study by categorization in two thirty member groups throw packet randomization. In control group, patients will be treated by baby shampoo and artificial tear drop, while in intervention group, simple eye ointment will be also applied in addition. Patients will be visited at 0, 2 and 4 weeks and collected data will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090923952N1**
Registration date: **2015-10-08, 1394/07/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-08, 1394/07/16

Registrant information

Name
Goldis Espandar
Name of organization / entity
Semnan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 23 3335 4359
Email address
goldisespandar@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellery of Research of Semnan University of Medical Sciences

Expected recruitment start date

2015-09-01, 1394/06/10

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of artificial tear drops and baby shampoos as treatments of dry eye syndrome(DES), with and without the administration of simple eye ointment

Public title

Effect of simple eye ointment on treatment of dry eye syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with DES clinical signs and symptoms which are confirmed by TBUT test; Patients must be between 20 and 60 years old; Patients must be diagnosed with DES for first time; Patients with idiopathic DES, not secondary types; Patients' workplace must be indoor; Patients must not take any ophthalmic drugs so far; Disease progression must be staged as mild or moderate; No history of undergoing refractive errors surgeries, utilizing contact eye lens and any drugs associated to DES; Informed consent for being involved in the study Exclusion criteria: Refusal to keep participating in the study; Intolerance to treatment

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Basij boulevard, Semnan

City

Semnan

Postal code

Approval date

2015-08-25, 1394/06/03

Ethics committee reference number

IR.SEMUMS.REC.1394.73

Health conditions studied

1

Description of health condition studied

dry eye syndrome

ICD-10 code

H04.1

ICD-10 code description

Lacrimal: cyst gland atrophy

Primary outcomes

1

Description

Patients remission rate

Timepoint

before Intervention, 2 weeks after intervention and 4 weeks after intervention

Method of measurement

International Dry Eye Workshop(DEWS)

Secondary outcomes

1

Description

Side effects of simple eye ointment

Timepoint

1 month after intervention

Method of measurement

Standard questionnaire

Intervention groups

1

Description

Control group: 1- Baby shampoo, every night, local, for 4 weeks 2- Artificial tear drop; in mild stages every 8 hours 1 drop in both eyes, and in moderate stages every 6 hours 1 drop in both eyes, for 4 weeks

Category

Treatment - Drugs

2

Description

Intervention group: 1- Baby shampoo, every night, local, for 4 weeks 2- Artificial tear drop; in mild stages every 8 hours 1 drop in both eyes, and in moderate stages every 6 hours 1 drop in both eyes, for 4 weeks 3- Simple eye ointment, every night, 0.5-1.0 cm2 in lower eyelid, in both eyes, for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan Kowsar Hospital

Full name of responsible person

Dr.Goldis Spandar, ophthalmologist
Street address
Kowsar Hospital, Golestan town, Semnan
City
Semnan

2

Recruitment center
Name of recruitment center
Ophthalmologist's Office
Full name of responsible person
Dr.Goldis Spandar, Ophthalmologist
Street address
Third floor, Sadaf complex, Saadi square, Semnan
City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellery of Research of Semnan University of Medical Sciences
Full name of responsible person
Dr.Rashidipour
Street address
Basij boulevard, Semnan
City
Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellery of Research of Semnan University of Medical Sciences
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
Semnan University of Medical Sciences
Full name of responsible person
Hamid Mirhoseiny
Position
Medical Student
Other areas of specialty/work
Street address
Third floor, 1 block, Shaghayegh square, Semnan
City
Semnan
Postal code
Phone
+98 23 3365 5404
Fax
Email
mirhoseiny.hamid@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr.Goldis Espandar
Position
Ophtalmologist
Other areas of specialty/work
Street address
Basij boulevard, Semnan
City
Semnan
Postal code
Phone
+98 23 3344 8996
Fax
Email
info@semums.ac.ir
Web page address
www.semums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Mohsen Pourazizi
Position
Medical Student
Other areas of specialty/work
Street address
Basij boulevard, Semnan
City
Semnan
Postal code
Phone
00
Fax
Email
m.pourazizi@yahoo.com
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