

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 cm<sup>2</sup> 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**

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**Position**

Medical Student

**Other areas of specialty/work**

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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*