

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Comparison of the Effectiveness of dripping breast milk in Infant's Eye and Academic Therapy in Neonates Lacrimal Duct Obstruction

#### Protocol summary

##### Study aim

The results of this study can be used as a simple and available treatment for congenital lacrimal duct obstruction disease, which is one of the most common complaints in infants referred to ophthalmology.

##### Design

Clinical trial without control group, Community-based and pragmatic , parallel groups, no-blinding, no-random, phase 2\_3 on 30 patients

##### Settings and conduct

Babies will be examined by a pediatrician in Jiroft and then referred to the ophthalmologist. First, the objectives of the research will be explained to the parents of the babies, and if they are willing to participate in the study and obtain informed consent, the data will be collected. In the first group, including academic treatment, eye drops and antibiotics, will be placed in the eye every six hours, and follow-up examinations will be continued every two weeks to one month and then monthly until the tear duct opens. In the second group, breast milk will be dripped into the eyes of the baby every six hours, and the follow-up examinations will be the same as the first group.

##### Participants/Inclusion and exclusion criteria

Babies with lacrimal duct obstruction who did not undergo any treatment after two weeks or no other diagnosis was considered for them and babies who were breastfed. Exclusion criteria will be age older than 11 months, performing other treatment methods such as probe, causing doctriocystitis or diagnosis of other eye diseases.

##### Intervention groups

People who enter the study will be randomly divided into 2 groups. In the first group, academic treatment, eye drops and antibiotics will be dripped into the baby's eyes, and in the second group, breast milk will be dripped into the baby's eyes.

##### Main outcome variables

Inflammation, redness and obstruction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230530058339N1**

Registration date: **2023-09-12, 1402/06/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-09-12, 1402/06/21**

Update count: **0**

##### Registration date

2023-09-12, 1402/06/21

##### Registrant information

##### Name

Fatemeh Amini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2231 4155

##### Email address

nooraamini30@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-21, 1402/01/01

##### Expected recruitment end date

2023-09-22, 1402/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effectiveness of dripping breast milk in Infant's Eye and Academic Therapy in Neonates Lacrimal Duct Obstruction

### Public title

Comparison of the Effectiveness of dripping breast milk in Infant's Eye and Academic Therapy in Neonates Lacrimal Duct Obstruction

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Infants who did not receive any treatment with lacrimal duct obstruction after two weeks No other diagnosis has been considered for them Breastfed babies

#### Exclusion criteria:

Age more than 11 months Using other treatment methods such as probe Development of dacryocystitis Diagnosis of other eye diseases

### Age

To **11 months** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

Not 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

Jiroft University of Medical Sciences

##### Street address

1st floor, Kotsar dormitory, Shahid Beheshti Blvd., not reaching Rozpiker intersection, El-Kengleb Square, Jiroft, kerman

##### City

Jiroft

##### Province

Kerman

##### Postal code

7861615765

### Approval date

2023-02-15, 1401/11/26

### Ethics committee reference number

IR.JMU.REC.1401.058

## Health conditions studied

### 1

#### Description of health condition studied

Nazolacrimal obstruction

#### ICD-10 code

H04.539

#### ICD-10 code description

Neonatal obstruction of unspecified nasolacrimal duct

## Primary outcomes

### 1

#### Description

Inflammation

#### Timepoint

At the beginning of the study and after two weeks and then every month until the inflammation is removed

#### Method of measurement

questionnaire

### 2

#### Description

Redness

#### Timepoint

At the beginning of the study and after two weeks and then every month until the redness is removed

#### Method of measurement

questionnaire

### 3

#### Description

Obstruction

#### Timepoint

At the beginning of the study and after two weeks and then every month until the obstruction is removed

#### Method of measurement

questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the intervention group, the breastfeeding will be dropped to the eye every six hours, and follow-up examinations will be performed every two weeks to one month and then monthly until the lacrimal duct is opened, which is a questionnaire.

**Category**

Treatment - Other

2**Description**

Control group:Academic treatment, eye drops and antibiotics will be dripped every six hours, and follow-up examinations will be continued every two weeks to one month and then monthly until the lacrimal duct opens.

**Category**

Treatment - Other

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Fatemeh amini

**Street address**

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**Email**

nooraamini30@gmail.com

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

Jeeroft University of Medical Sciences

**Full name of responsible person**

Dr Hedieh Askarpur

**Street address**

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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**

Jeeroft 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**

Jeeroft University of Medical Sciences

**Full name of responsible person**

Fatemeh Amini

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

West 3rd Floor , No. 12 ,Farzin Alley ,Amirnia St ,Shahid Panahinia St., Heravi Square, Pasdaran ,Tehran

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Jeeroft University of Medical Sciences

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Jeeroft University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Amini  
**Position**  
Medical Student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available