Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 doctoriocystitis 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 drippng 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
1st floor, Kotsar dormitory, Shahid Beheshti Blvd., not reaching Rozpiker intersection, El-Kengleb Square, Jiroft , kerman
City
Jiroft
Province
Kerman
Postal code
7861615765
Phone
+98 921 650 0572
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
1st floor, Kosar dormitory, Shahid Beheshti Blvd , Not reaching Ruzpeikar intersection, El-Enghelab Square, Jiroft , kerman
City
Jiroft
Province
Kerman
Postal code
7861615765
Phone
+98 34 4331 6311
Email
nooraamini30@gmail.com
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
City
Tehran
Province
Tehran
Postal code
1665883418
Phone
+98 21 2231 4155
Email
nooraamini30@gmail.com

Person responsible for scientific 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

City

Tehran

Province

Tehran

Postal code

1665883418

Phone

+98 21 2231 4155

Email

nooraamini30@gmail.com

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

General Practitioner

Street address

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

City

Tehran

Province

Tehran

Postal code

1665883418

Phone

+98 21 2231 4155

Email

nooraamini30@gmail.com

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