Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Comparing the Effects of the Breast milk and Sucrose on Pain and Coping with Stress during Retinopathy Examination of Premature Infants

Protocol summary

Study aim
Comparing the Effects of the Breast milk and Sucrose on Pain and Coping with Stress during Retinopathy Examination of Premature Infants

Design
This study will conductewith 63 preterm infants (breast milk group=21, sucrose group=21, and control/distilled water group=21). Convenience sampling and random assignment are sealed envelope. A clinical trial with a community-based and pragmatic control group, with parallel, double blinded, and randomized groups.

Settings and conduct
Sampling place is in Farabi Hospital. Two minutes before the examination, 0.5 mililiter per kilogram of sucrose solution or breast milk or distilled water is fed to the infant by syringe. starting five minutes before the examination, up to fifteen minutes later, a video recording will be made. The infants' Vital signs will be recorded in five steps (5 minutes before the examination, just starting and in minutes 5, 10 and 15 after examination). Pain and stress assessment is also done by video observation using ALPS-Neo pain and stress scale.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Preterm infants born at or below 32 weeks of gestational age and birth weight at or below 2000 grams. Non-entry criteria: infants diagnosed with a congenital anomaly.

Intervention groups
In breast milk group, two minutes before the examination, 0.5 mililiter per kilogram of breast milk is fed to the infant by syringe. In sucrose group, two minutes before the examination, 0.5 mililiter per kilogram of sucrose 24% is fed to the infant by syringe. In distilled water group, two minutes before the examination, 0.5 mililiter per kilogram of distilled water is fed to the infant by syringe.

Main outcome variables
Pain and coping with stress score during retinopathy examinations in preterm infants.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180718040523N1**
Registration date: **2018-08-04, 1397/05/13**
Registration timing: **prospective**

Last update: **2018-08-27, 1397/06/05**
Update count: **1**

Registration date
2018-08-04, 1397/05/13

Registrant information

Name
Aida Safaiee Fakhr

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3377 9923

Email address
a-safaieef@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-05, 1397/05/14

Expected recruitment end date
2018-10-06, 1397/07/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparing the Effects of the Breast milk and Sucrose on Pain and Coping with Stress during Retinopathy Examination of Premature Infants

Public title
Effect of Breast milk and Sucrose on Pain and Coping with Stress

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Premature infants born at or below 32 weeks of gestational age Preterm infants that born with a birth weight at or below 2000 gram.

Exclusion criteria:
Preterm infants diagnosed with a congenital anomaly, hydrocephalus, necrotizan enterocolitis, indirect hyperbilirubinemia.

Age
From **28 days** old to **60 days** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **63**

Randomization (investigator's opinion)
Randomized

Randomization description
Convenience sampling (Anyone who had the inclusion criteria entered the study). and random assignment are sealed envelope (Samples of sucrose, breast milk and distilled water are placed inside the envelopes, and before sampling, one of the envelopes is selected by the secretary and the intervention is done).

Blinding (investigator's opinion)
Double blinded

Blinding description
An eye examiner will be unaware of the type of intervention. The parents and, subsequently, the infant will be unaware of the type of substance received. Evaluators the film will be unaware of the intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Joint Organizational Ethics Committee of Faculty of Nursing and Midwifery and Rehabilitation, Tehran

Street address
Nosrat street,Tohid square

City
Tehran

Province
Tehran

Postal code
3471874439

Approval date
2018-03-13, 1396/12/22

Ethics committee reference number
IR.TUMS.FNM.REC.1397.052

Health conditions studied

1

Description of health condition studied
Retinopathy of Prematurity

ICD-10 code
H35.1

ICD-10 code description
Retinopathy of prematurity

Primary outcomes

1

Description
pain

Timepoint
5 minutes before examination- the moment of starting examination, minutes 5, 10, 15

Method of measurement
ALPS-Neo Pain and Stress assessment Scale

Secondary outcomes

1

Description
Coping with stress

Timepoint
5 minutes before examination, the moment of the examination, minutes 5, 10, 15

Method of measurement
with ALPS-Neo pain and stress assessment scale

Intervention groups

1

Description

Intervention group: In this group infants 0.5 mililiter per kilogram from their mother milk recive orally 2 minutes before examination

Category

Treatment - Other

2

Description

Intervention group: In this group infants 0.5 mililiter per kilogram from sucrose 24% sulotion recive orally 2 minutes before examination

Category

Treatment - Other

3

Description

Control group: In this group infants 0.5 mililiter per kilogram from distilled water recive orally 2 minutes before examination

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Farabi hospital

Full name of responsible person
Aida Safaiee Fakhr

Street address
Qazvin Square, karegar street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Vida kardan

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Nosrat Street, Tohid Square

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Aida Safaiee Fakhr

Position
Student

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Latest degree
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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