

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The relationship between oropharyngeal administration of breast milk and early outcomes in premature infants with a birth weight of less than 1500 grams.

Protocol summary

Study aim

Comparison of early outcomes due to oropharyngeal administration or non-administration of breast milk in premature infants admitted to the neonatal intensive care unit

Design

A clinical trial with case and control group, single-blind, randomized, on 70 patients. RAS software is used for randomization.

Settings and conduct

This study will be conducted in a single blind way in the neonatal intensive care unit of Mahdiah Hospital in Tehran. In the intervention group, 8 drops of mother's expressed milk will be dripped on the sides of the oral mucosa every 3 hours. The intervention will continue until the start of oral feeding. The control group will not receive this milk in this way. Due to the type of intervention and lack of placebo, blinding will be done only for the group of outcome assessors and data analysts.

Participants/Inclusion and exclusion criteria

All very low birth weight infants admitted to the NICU are enrolled. Inclusion criteria are the absence of severe maternal malformations, weighing less than 1,500 grams, the ability to start our protocol in the first 96 hours of life. Exclusion criteria are congenital anomalies and gastrointestinal problems that are contraindicated in nutrition, such as esophageal atresia, as well as asphyxia in infants, maternal AIDS, maternal substance abuse, and triplets or more.

Intervention groups

The intervention group is given oral colostrum according to the protocol from the first day of birth until the start of oral feeding, and the control group is not given oral milk until the start of oral feeding.

Main outcome variables

Intraventricular hemorrhage, Bronchopulmonary

dysplasia, Ventilator-induced pneumonia, Premature retinopathy, Sepsis, Duration of hospitalization, Death, Necrotizing enterocolitis, Duration to reach 150 cc per kilogram feed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220424054629N1**

Registration date: **2023-05-09, 1402/02/19**

Registration timing: **prospective**

Last update: **2023-05-09, 1402/02/19**

Update count: **0**

Registration date

2023-05-09, 1402/02/19

Registrant information

Name

Sedigheh Tehranchi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2274 9212

Email address

drsedighehtehranchi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The relationship between oropharyngeal administration of breast milk and early outcomes in premature infants with a birth weight of less than 1500 grams.

Public title
The relationship between oropharyngeal administration of breast milk and early outcomes in premature infants with a birth weight of less than 1500 grams.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
no sever congenital anomalies birth weight below 1500 gr capability of protocol administration in the first 96 hours
Exclusion criteria:
Congenital Anomalies Gastrointestinal problems that are for contraindication to nutrition, such as esophageal atresia Neonatal asphyxia Maternal HIV infection Maternal history of substance abuse Triple gestation or more

Age
From **1 day** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
The classification of the samples to be assigned to the treatment groups will be done in a block random manner. The randomization unit is considered individual. RAS statistical software, block randomization tool will also be used to determine the sequence of blocks. The sealed cover letter will be used for allocation concealment. We consider the capacity of the blocks as 4 and then we write all the possible permutations for this block, which are defined as follows. (1: ABAB) and (2: AABB) and (3: BBAA) and (4: BABA) and (5: ABBA) and (6: BAAB) By means of statistical software, we randomly select one of the numbers of permutations and consider the block corresponding to it. For example, if the first random selection of block 2 is selected, the first person will receive treatment A, the second person will receive treatment A, the third person will receive treatment B, and the fourth person will receive treatment B. To reach a sample size of 61 per group, we continue this sequence 30 times. After selecting all the blocks, we randomly

assign indices B and A to one of the treatment groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
It is not possible to blind the caregivers who drip milk into the baby's mouth (intervention group) and do not have this intervention (control group). Considering that this plan does not have a placebo, the baby's family will also know whether their baby is in the intervention group or the control group. The intervention and control group will be known as A and B, and only the data analyst and outcome assessor will not know whether A is the intervention group or the control.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of medical sciences .Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2021-02-21, 1399/12/03

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.1271

Health conditions studied

1

Description of health condition studied

Necrotizing enterocolitis

ICD-10 code

ICD-10 code description

2

Description of health condition studied

oral colostrum

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Neonatal sepsis

ICD-10 code

ICD-10 code description

4

Description of health condition studied

Retinopathy of prematurity

ICD-10 code

ICD-10 code description

5

Description of health condition studied

Intraventricular hemorrhage

ICD-10 code

ICD-10 code description

6

Description of health condition studied

Bronchopulmonary dysplasia

ICD-10 code

ICD-10 code description

7

Description of health condition studied

Neonatal death

ICD-10 code

ICD-10 code description

8

Description of health condition studied

ventilator associated pneumonia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

neonatal death

Timepoint

During hospitalization

Method of measurement

Clinical documentation

2

Description

Neonatal Sepsis

Timepoint

During hospitalization

Method of measurement

Clinical and paraclinic documentation

3

Description

Retinopathy of prematurity

Timepoint

During hospitalization

Method of measurement

Physical examination

4

Description

Intraventricular hemorrhage

Timepoint

During hospitalization

Method of measurement

Brain sonography

5

Description

Ventilator associated pneumonia

Timepoint

During hospitalization

Method of measurement

Clinical and paraclinical documentaion

6

Description

Time to reach fullfeed

Timepoint

During hospitalization

Method of measurement

Clinical documentaion

7

Description

Necrotizing entrocolitis

Timepoint

During hospitalization

Method of measurement

Clinical documentaion

8

Description

Hospitalization duration

Timepoint

During hospitalization

Method of measurement

Clinical doccumentation

9

Description

Oral colostrom intake

Timepoint

During the first 96 hours of life

Method of measurement

Clinical documentation

10

Description

Bronchopulmonary dysplasia

Timepoint

During hospitalization

Method of measurement

Clinical and paraclinic documentation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, babies will receive 8 drops equivalent to 0.2 cc of warm milk expressed by their mother every 3 hours. This amount of milk will be dripped 4 drops on each side of the mouth by the baby nurse with a 1 cc needle less syringe. This milk will be separate from the amount of milk that the baby will receive by gavage with feeding tube on a routine basis for feeding, usually from the third day of birth. This intervention will continue until the baby starts oral feeding. That is, when the baby is able to receive milk directly through the mouth and not by gavage.

Category

Treatment - Other

2

Description

Control group: In this group of infants, according to common care, they will not receive any milk by mouth until the start of oral feeding. Of course, this intervention will be separate from the volume of milk, which will be received routinely for feeding, usually from the third day of the baby's birth, in the form of gavage with a feeding tube.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Hospital

Full name of responsible person

khoshnood shariati maryam

Street address

Fadayian eslam st, Shoush sq, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sedigheh Tehrani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

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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