

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the effect of oropharyngeal colostrum administration from the first day of life in very low birth weight premature infant

Protocol summary

Study aim

Evaluating the effect of oropharyngeal colostrum administration from the first day of life in very low birth weight premature infant

Design

A concealed, randomized, blinded, clinical trial with a parallel group design of 50 patients, enrolled between November 2019 and November 2020. 2-3 RCT Phase.

Settings and conduct

The study was conducted at Shohada-e-Tajrish Hospital's NICU in Tehran. Newborn babies were randomly divided into two groups. Group Control was performed Minimal Enteral Feeding after 72 hours of birth and exposure group was received 0.2 cc breast milk (colostrum) every 3 hours orally from the first hours after birth. Double-blinded study, which the patients, the nurses, the conductors, and the analyst _who later joined the research team and was not a member initially _ were not aware.

Participants/Inclusion and exclusion criteria

Birth Weight lower than 1500 grams; Birth Weight beyond 1500 grams Gestational Age lower than 32 weeks; Gestational Age more than 32 weeks Newborn without congenital abnormalities; congenital anomalies Newborn without Asphyxia; Asphyxiated

Intervention groups

Newborn babies were randomly divided into two groups. Group Control was performed Minimal Enteral Feeding after 72 hours of birth and exposure group was received 0.2 cc breast milk (colostrum) every 3 hours orally from the first hours after birth. Its effects on neonatal growth indices, infections, Hospital duration, full fed time and mortality will be recorded.

Main outcome variables

Gestational Age; Birth Weight; Baby Sex; Length of hospitalization; Oral tolerance; Weight; Infection; Death.

General information

Reason for update

Acronym

LBW

IRCT registration information

IRCT registration number: **IRCT20141118019991N2**

Registration date: **2019-10-16, 1398/07/24**

Registration timing: **prospective**

Last update: **2019-10-16, 1398/07/24**

Update count: **0**

Registration date

2019-10-16, 1398/07/24

Registrant information

Name

Saharnaz Talebiyan

Name of organization / entity

Tehran university of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-21, 1398/08/30

Expected recruitment end date

2020-11-19, 1399/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of oropharyngeal colostrum administration from the first day of life in very low birth weight premature infant

Public title

Evaluating the effect of oropharyngeal colostrum in very low birth weight premature infant.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Birth Weight lower than 1500 grams Gestational Age lower than 32 weeks Infant without congenital abnormalities. No evidence of asphyxia.

Exclusion criteria:

Birth Weight more than 1500 grams. Gestational Age more than 32 weeks. Infant with congenital abnormalities. Infant with asphyxia. Need for resuscitation after birth. Drug Abuser mother. Mother who has HIV positive test. Mothers who are Cytomegal Virus seropositive

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Utilizing "RAS", permuted randomization was conducted on the sample population. Permuted Block Randomization of the Individual type was performed. The allocation concealment was done by The Data Safety and Monitoring Center of Shohadaye Tajrish Hospital's Clinical Research Development Department.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was a double-blinded study in which the patients, the nurses, the conductors, and the analyst _who later joined the research team and was not a member initially _ were not aware of the sampling procedures and the method by which randomly chosen treatments were administered to the patients. The method was carried out and authorized by "The Safety and Monitoring Committee."

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

Shohada Hospital, Tajrish Square

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2019-07-06, 1398/04/15

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.133

Health conditions studied

1

Description of health condition studied

Sepsis

ICD-10 code

A41.9

ICD-10 code description

Sepsis, unspecified organism

2

Description of health condition studied

Narcotizing Enterocolitis

ICD-10 code

P77.9

ICD-10 code description

Necrotizing enterocolitis in newborn, unspecified

3

Description of health condition studied

Mortality

ICD-10 code

R99

ICD-10 code description

Ill-defined and unknown cause of mortality

4

Description of health condition studied

Hospitalization Duration

ICD-10 code

ICD-10 code description

5

Description of health condition studied

Full Fed time

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sepsis Early or Late Onset, clinical or Para-clinical Sign and Symptoms.

Timepoint

Multiple clinical Evaluation per day, and if needed also Para-clinical evaluation

Method of measurement

Clinical and Para-clinical Signs and Symptoms

2

Description

Clinical and Para-clinical sign of Necrotizing Enterocolitis

Timepoint

Multiple clinical Evaluation per day, and if needed also Para-clinical evaluation

Method of measurement

Clinical and Para-clinical Signs and symptoms.

3

Description

Hospitalization Duration

Timepoint

Hospitalization Duration by days number at discharge.

Method of measurement

Hospitalization Duration

Secondary outcomes

1

Description

Mortality

Timepoint

the time of Dead

Method of measurement

Vital sign not recorded and no respond to Resuscitation

2

Description

Weight gain progress

Timepoint

Daily

Method of measurement

SEGA digital scale

3

Description

The time to reach full enteral feeding (120 cc / kg)

Timepoint

Daily

Method of measurement

It was calculated every day by the neonatologist and Neonate feeding tolerance .

Intervention groups

1

Description

Intervention group: Oropharyngeal administration of 0.2 cc Colostrum was started at the first hour of life, It was given every 3 hour for 3 days.

Category

Treatment - Other

2

Description

Control group: Breast Milk Minimal Enteral Feeding administration was started after 72 hours of life.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Saharnaz Talebiyan

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Shohada Hospital, Tajrish Square, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice-Chancellor in Research Affairs

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7 th Floor, Bldg No.2 SBUMS, Arab Ave, Daneshjoo Blvd, Velenjak

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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
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
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Position
Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

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

No - There is not 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

No - There is not a plan to make this available

