Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 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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+98 21 6119 2407

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

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1985717443
Phone
+98 21 2387 2206
Email
info@sbmu.ac.ir
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
Full name of responsible person
Saharnaz Talebiyan
Position
Assistant Professor
Latest degree
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Pediatrics
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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

Data Dictionary	Not applicable