

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Investigating Prognosis of Early Feeding with Breast milk-Cells in Premature infants

Protocol summary

Study aim

Investigating prognosis of early feeding with breastmilk-cells in premature infants

Design

Case group : Include 64 premature babies, with birth weight less than 1800 grams and can not tolerate their own mother breast milk. Control group: This group will be fed according to the routine ward protocol. They were selected randomly and by using special statistical tables. After an informative consent from parents.

Settings and conduct

This study will be done in Mahdiah Hospital and in the NICU ward. For the case group, we will ask the mothers to pump their milk and collected in a sterile tube with the supervision of trained personnel. This fresh milk will be centrifuged and the upper layer which contains fat and protein will be separated. The rest of the tube that contains breast milk cells will be fed by N.G.Tube or PO.

Participants/Inclusion and exclusion criteria

All premature infants born with birth weight less than 1800 g , with parental consent is entered into the study . If the baby has severe congenital anomalies or severe and fatal illness, will be excluded from the study.

Intervention groups

Case group: Include infants unable to bear breast milk after birth. For this group, the breast milk is centrifuged and the separated cells are fed to the baby after separating the fat and protein layer. Breastfeeding begins as other infants, when they can tolerate the whole milk. Control group: Include infants selected by statistical tables and breastfeeding will be started according to usual ward protocols.

Main outcome variables

In addition to demographic variables, age of breast feeding and feeding tolerance, and some complications like BPD, NEC, ROP... will be evaluated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190228042868N1**

Registration date: **2019-05-25, 1398/03/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Mohammad Kazemian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating Prognosis of Early Feeding with Breast milk-Cells in Premature infants		Medical Sciences	
Public title		Street address	
Investigating Prognosis of Early Feeding with Breast milk-Cells in Premature infants		Mofid Children Hospital, Shariati St.,Tehran, Iran	
Purpose		City	
Treatment		Tehran	
Inclusion/Exclusion criteria		Province	
Inclusion criteria:		Tehran	
All the neonates that were born with a birth weight less than 1800 grams		Postal code	
Exclusion criteria:		1546815514	
Parental dissatisfaction with the implementation of this study Failure to prepare breast milk for various reasons Congenital severe anomalies The presence of any serious and fatal illness that is in conflict with life Severe Prematurity (less than 25 weeks)		Approval date	
Age		2018-11-29, 1397/09/08	
From 1 day old to 90 days old		Ethics committee reference number	
Gender		IR.SBMU.RETECH.REC.1397.1287	
Both		Health conditions studied	
Phase		1	
2		Description of health condition studied	
Groups that have been masked		Necrotizing enterocolitis (NEC)	
- Participant - Outcome assessor		ICD-10 code	
Sample size		P77	
Target sample size: 128		ICD-10 code description	
Randomization (investigator's opinion)		Necrotizing enterocolitis of newborn	
Randomized		2	
Randomization description		Description of health condition studied	
According to statistical method : Block randomization		Bacterial sepsis of newborn	
Blinding (investigator's opinion)		ICD-10 code	
Single blinded		P36	
Blinding description		ICD-10 code description	
We urge the mothers of both groups to express their own milk.This action will stimulate and secrete more milk for mothers in the coming days and is recommended. Because the low-birth weight infants can not tolerate feeding in routine therapy, the extracted cells are given to the case group. As time goes on, nutrition will be started for both groups, based on the routine (clinical and special condition).		Bacterial sepsis of newborn	
Placebo		3	
Not used		Description of health condition studied	
Assignment		Retinopathy of prematurity	
Parallel		ICD-10 code	
Other design features		H35.1	
Secondary Ids		ICD-10 code description	
empty		Retinopathy of prematurity	
Ethics committees		4	
1		Description of health condition studied	
Ethics committee		Bronchopulmonary dysplasia	
Name of ethics committee		ICD-10 code	
Ethic committee of shahid Beheshti University of		P27.1	
		ICD-10 code description	
		Bronchopulmonary dysplasia originating in the perinatal period	
		Primary outcomes	
		1	
		Description	
		Duration of hospital stay	
		Timepoint	
		The whole period of admission is evaluated	
		Method of measurement	

Based on observation and examination and questionnaire records.

2

Description

2-Comparison of the total feeding time in the newborn

Timepoint

From birth to full feeding

Method of measurement

Evidence available in the clinical file and based on the day

3

Description

Incidence of necrotizing enterocolitis

Timepoint

The disease occurs most of the time with the onset of nutrition and during the hospital stay.

Method of measurement

According to the "Bell's criteria"

4

Description

Time required for the respirator

Timepoint

Duration of treatment with respirator.

Method of measurement

Evidence available in the clinical file and based on the day

5

Description

Prevalence of retinopathy of prematurity

Timepoint

Ophthalmologic examination for all newborns will be done in about 1 month of age.

Method of measurement

It will be calcified according the extent of the vessels of the bottom of the eye.

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, feeding with lactating cells started by separating of the fat and protein layer. these neonate can not tolerate whole breast milk.

Category

Treatment - Other

2

Description

Control group: Babies who received routine nursing care

and after a few days breastfeeding will be started.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdiah Maternity Hospital

Full name of responsible person

Kazemian Mohammad

Street address

Fadaeian Eslam ave.- Shoosh Squ.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zarghi Afshin

Street address

Next to Taleghani Hospital, Velengak, Chamran high way

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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
Full name of responsible person
Shafiee Rodsari Mohammad
Position
Sub-speciality resident
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All individual data will be available after the publication of the article, after making the participants identifiable.

When the data will become available and for how long

Immediately after publication.

To whom data/document is available

It will be available for all researchers.

Under which criteria data/document could be used

To promote breastfeeding and the importance of the compounds and cells in it.

From where data/document is obtainable

Requests sent to the author's e-mail or other

corresponders will be answered as soon as possible.

What processes are involved for a request to access data/document

Simple request sent to the corresponding author's email.

Comments

Since one of our goals is promoting breastfeeding, we will do our best to publish our findings.