Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of pasteurized donor human milk in plastic and glass containers on the level of some hormones and anthropometric indexes in preterm neonate in neonatal intensive care units

Protocol summary

Study aim
Determining the effect of pasteurized human milk in plastic and glass containers on the level of some hormones and anthropometric indicators of preterm neonates

Design
A two-group randomized clinical trial

Settings and conduct
After approving the project, the researcher went to Shahid Beheshti and Al-Zahra hospitals, and based on inclusion criteria, samples were allocated to two intervention and control groups. Then the neonate's feeding continues for 4 weeks using donated milk that has been pasteurized in two containers. After that, a request for tests (estrogen and growth hormones, immunoglobulin A) is given after recording the neonatologist order in the neonate's file. Evaluation of thyroid hormone level in preterm neonate is one of the routine screening cases and the results of which will be used in the present study. The evaluation of anthropometric index will be done by the researcher under the same conditions.

Participants/Inclusion and exclusion criteria
inclusion criteria neonates 26-32 weeks of pregnancy,Don't have life-threatening congenital abnormalities,Do not have chromosomal and asphyxia disorders,neonates who have at least 70% of their nutrition with donor milk during 24 hours,neonates who received donor milk up to 4 weeks after birth,Do not have a positive blood culture at the beginning of hospitalization. exclusion criteria Transferring the neonate to different hospitals from the research environment,Death of a neonate,Parents' refusal to participate in the study,Hospitalization period less than 4 weeks

Intervention groups
Preterm neonates receiving donor milk in a plastic and glass container

Main outcome variables
estrogen and growth hormones, immunoglobulin A, ,Thyroid hormone, anthropometric index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200714048101N1**
Registration date: **2024-01-04, 1402/10/14**
Registration timing: **prospective**

Last update: **2024-01-04, 1402/10/14**
Update count: **0**

Registration date
2024-01-04, 1402/10/14

Registrant information

Name
Zeinab Hemati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 7624

Email address
z.hemate@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of pasteurized donor human milk in plastic and glass containers on the level of some hormones and anthropometric indexes in preterm neonate in neonatal intensive care units

Public title

Investigating the effect of the type of containers used in the human milk pasteurization process on preterm neonate

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

neonates 26-32 weeks of pregnancy Does not have life-threatening congenital anomalies (digestive, cardiac, neurological...). Do not have chromosomal disorders. Do not have asphyxia. Neonates who are fed at least 70% by donor human milk during 24 hours. Breast milk that has not been pasteurized for more than 72 hours since leaving the refrigerator at a temperature of 4 degrees Celsius. Donor milk that has not been stored for more than 1 month in the freezer at -20 degrees Celsius. donor milk that has been used up to 48 hours after leaving the frozen state. Neonates who have received donor milk up to 4 weeks after birth. Do not have a positive blood culture at the beginning of hospitalization.

Exclusion criteria:

Transferring the neonate to different hospitals from the research environment Death of a neonate Parents' refusal to participate in the study Hospitalization period less than 4 weeks

Age

From **28 days** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are allocated to two interventions (plastic storage container) and control (glass storage container) groups based on the random permutation block method. Random sequence is generated using Blockrand package and R software.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib street, faculty of nursing and midwifery

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2023-12-31, 1402/10/10

Ethics committee reference number

IR.MUI.NUREMA.REC.1402.165

Health conditions studied

1

Description of health condition studied

preterm neonates feeding with donor human milk

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Estrogen

Timepoint

four weeks after feeding

Method of measurement

laboratory results

Secondary outcomes

1

Description

Estrogen, growth and thyroid hormones, immunoglobulin A, anthropometric index

Timepoint

four week after feeding

Method of measurement

laboratory results

Intervention groups

1

Description
Intervention group: neonates receiving donor milk in a plastic container
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra and Shahid Beheshti hospitals
Full name of responsible person
Dr Zeinab Hemati
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Hazar Jarib Street, Isfahan University of Medical Sciences, School of Nursing and Midwifery
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Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Dr Zeinab Hemati
Position
Assistant professor
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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
Information about the outcome of the study

When the data will become available and for how long
After finishing the study

To whom data/document is available
Researchers in the field of neonates

Under which criteria data/document could be used
Using the results in other studies by mentioning the reference

From where data/document is obtainable
nastaran hassanvand

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

Comments