Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation the effect of pasteurization of mothers own milk contaminated with cytomegalovirus on clinical and laboratory outcomes of very premature infants admitted to selected hospitals of Isfahan University of Medical Sciences in 2026

Protocol summary

Study aim
Investigation the effect of pasteurization of mothers own milk contaminated with cytomegalovirus on clinical and laboratory outcomes of very premature infants

Design
Two-group randomized clinical trial

Settings and conduct
The present study is a randomized clinical trial in very preterm infants with a gestational age ≤28 weeks hospitalized in the NICU of selected hospitals of Isfahan University of Medical Sciences. The researcher first identifies mothers with a gestational age ≤28 weeks who are at risk of preterm delivery. A blood sample is obtained from the mother, and if the PCR result is positive, after the infant is admitted to the NICU, a urine sample is sent to the laboratory for evaluation for congenital cytomegalovirus infection in the first week of hospitalization and before the start of breastfeeding, and if the test result is negative, the infant is entered into the study. Then, in the intervention group, the infant is fed with their own mother's milk after registering the physician's request, which has undergone the pasteurization process, and the control group, infants who receive breast milk without undergoing the pasteurization process. The infant is fed for 4-6 weeks, and then a urine sample is obtained for evaluation of CMV PCR for acquired infection.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Preterm infants ≤ 28 weeks, No life-threatening congenital abnormalities,infants in the two groups who received at least 60% of their nutrition with pasteurized or unpasteurized breast milk.Exclusion criteria:Transfer of the infant to a hospital other than the study setting، Death of the infant

Intervention groups
Intervention (pasteurized MOM milk) and control (unpasteurized MOM milk)

Main outcome variables
PCR CMV

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200714048101N2**
Registration date: **2026-06-29, 1405/04/08**
Registration timing: **prospective**

Last update: **2026-06-29, 1405/04/08**
Update count: **0**

Registration date
2026-06-29, 1405/04/08

Registrant information

Name
Zeinab Hemati

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-07-11, 1405/04/20

Expected recruitment end date
2027-09-11, 1406/06/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation the effect of pasteurization of mothers own milk contaminated with cytomegalovirus on clinical and laboratory outcomes of very premature infants admitted to selected hospitals of Isfahan University of Medical Sciences in 2026

Public title
the effect of pasteurization of mothers own milk contaminated with cytomegalovirus on clinical and laboratory outcomes of very premature infants
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
*Preterm infants ≤ 28 weeks of gestation based on the first day of the last menstrual period. *Singleton or multiple pregnancies. *Vaginal or cesarean delivery. *No life-threatening congenital anomalies (based on evidence in the newborn's file: gastrointestinal, cardiac, neurological, etc.). *No chromosomal abnormalities (based on the newborn's file). *No asphyxia (based on the neonatologist diagnosis and the newborn's file).* Based on the volumes recorded in the intensive care unit sheets, infants in two groups who received at least 60% of their nutrition with pasteurized mom milk or unpasteurized mom milk.* At least 4-6 weeks of infant nutrition according to the assigned group. *Infants who did not have a positive blood culture at the beginning of hospitalization (based on the file).* Infants whose PCR-CMV result was negative in the first week of life and before the start of enteral feeding.
Exclusion criteria:
*Transfer of the infant to a different hospital from the study setting, *Emergence of unrelated acute illnesses requiring interruption of enteral feeding or change of treatment protocol, *Death of the infant, *Parent withdrawal from participation in the study
Age
From **7 days** old to **35 days** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
Infants who meet the study eligibility criteria and whose medical records indicate breastfeeding, based on the attending physician's recommendation and parental consent, will first be enrolled in the study using a convenience sampling method from the selected hospitals. They will then be randomly allocated to either the intervention or control group using the permuted block randomization method. The randomization sequence will be generated using the Blockrand package in the R software.
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding is possible and can be implemented spontaneously for the neonates, but not for the treatment team due to ethical considerations. Therefore, single-sided blinding (blinding of the outcome assessor and statistical analyst to group allocation) is considered.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences
Street address
Hezarjerib St, Isfahan University of Medical Sciences Isfahan, Iran
City
Esfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2026-06-27, 1405/04/06
Ethics committee reference number
IR.MUI.NUREMA.REC.1405.050

Health conditions studied

1

Description of health condition studied
cytomegalovirus
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

CMV infection

Timepoint

Before starting breastfeeding and 4 weeks after

Method of measurement

Urine PCR CMV

Secondary outcomes

1

Description

Necrotizing enterocolitis, lung dysplasia, retinal damage, leukomalacia, jaundice, liver enzyme levels, counts (neutrophils, platelets, leukocytes), CRP, and length of stay

Timepoint

Until discharge time

Method of measurement

Data in the newborn's file

Intervention groups

1

Description

Intervention group: Infants receiving pasteurized MOM milk

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Selected Hospitals of Isfahan University of Medical Sciences

Full name of responsible person

Zeinab Hemati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Vice President for Research

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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

Zeinab Hemati

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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