

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of participation in the oral-pharyngeal administration of colostrum on anxiety of mothers of preterm infants admitted to neonatal intensive care unit

Protocol summary

Study aim

Determining the effect of participation in the oral-pharyngeal administration of colostrum on the anxiety of mothers of premature babies hospitalized in the neonatal intensive care unit

Design

Randomized clinical trial, the sample size is 148 people, the random list of people is prepared through the website <http://randomisation.ir>.

Settings and conduct

This research is a clinical trial that is conducted in Shahid Akbarabadi State Hospital in Tehran. The researcher invites eligible research units to cooperate in the study. Eligible mothers will be randomly divided into intervention and control groups. Before and 24 hours after the intervention, the situational trait anxiety questionnaire is completed by the mothers of both groups.

Participants/Inclusion and exclusion criteria

Mothers of premature babies

Intervention groups

During the first 24 hours after birth, the mothers of the intervention group deliver their expressed milk to the researcher three times a day every 4 hours during the prescribed time for 48 hours, and the researcher injects the milk with a 1 ml syringe without a needle. It is given to the baby, in the presence of the mother and under the supervision of a neonatologist. The tip of the syringe is placed in the baby's mouth along the right buccal mucosa towards the oropharynx and the volume of 0.1 ml is prescribed, and without removing the syringe from the baby's mouth, 0.1 ml is also administered in the left buccal. Mothers in the control group are not given milk to feed their babies, and according to the department's routine, when the doctor orders them to start breastfeeding.

Main outcome variables

Maternal anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200120046200N3**

Registration date: **2022-11-14, 1401/08/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-16, 1401/11/27**

Update count: **2**

Registration date

2022-11-14, 1401/08/23

Registrant information

Name

Seyedeh saeedeh Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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mousavi.ss@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of participation in the oral-pharyngeal administration of colostrum on anxiety of mothers of preterm infants admitted to neonatal intensive care unit

Public title

The effect of participation in the oral-pharyngeal administration of colostrum on anxiety of mothers of preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages 18 years and above Willingness to breastfeed Understanding and speaking ability in Persian language Willing to manually express milk or use of a manual or electric breast pump in the first 24 hours after delivery mother's presence in the hospital during the study period Gestational age less than 32 weeks or birth weight less than 1500 grams Being NPO for infant Stable vital signs for infant

Exclusion criteria:

Mother's suffering from psychological disorders requiring medication based on mother's self-report History of drug and psychoactive abuse Surgery or breast problems such as abscess, inverted nipple, mastitis or cancer Having diseases contrary to breastfeeding such as AIDS, active pulmonary tuberculosis Occurrence of stressful events during the study period Hospitalization of the mother after delivery in departments other than postpartum No grade 3 and 4 intraventricular hemorrhage Absence of pH less than 6 in the fifth minute after birth Absence of abnormalities in the infant based on medical records

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **148**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible samples will be continuously included in the study, then the allocation will be done in two groups of test and control randomly using the 4-block method with placement. The random list of people is prepared through the website <http://randomisation.ir>.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Fifth floor, Headquarters., Iran University of Medical Sciences., Hemmat Highway between Chamran and Sheikh Fazlullah

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2022-10-04, 1401/07/12

Ethics committee reference number

IR.IUMS.REC.1401.555

Health conditions studied**1****Description of health condition studied**

The effect of participation in the oral-pharyngeal administration of colostrum on the anxiety of mothers of premature babies hospitalized in the neonatal intensive care unit

ICD-10 code

Z63.7

ICD-10 code description

Other stressful life events affecting family and household

Primary outcomes**1****Description**

Maternal anxiety

Timepoint

Before the intervention, 24 hours after the intervention

Method of measurement

State Trait Anxiety Inventory(STAI)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: During the first 24 hours after giving

birth, the mothers of the test group deliver their expressed milk to the researcher three times a day every 4 hours during the prescribed time in the morning and evening shifts for 48 hours, and the researcher injects the expressed colostrum with a 1 ml syringe, without The head of the needle is given to the baby three times a day, in the presence of the mother and under the supervision of a newborn doctor. In this way, the tip of the syringe is placed in the baby's mouth along the right buccal mucosa and is directed to the oropharynx, and the volume of 0.1 ml is prescribed, and without removing the syringe from inside the baby's mouth, the left buccal is also 0.1 ml. ml is repeated in the mentioned method. A total of 0.2 ml is prescribed in each session. Mothers in the control group do not receive milk to feed the baby, and they express their milk and deliver it to the neonatal intensive care unit according to the department's routine when the doctor orders to start breastfeeding and feeding the baby.

Category

N/A

2

Description

Control group: Mothers in the control group are not given milk to feed the baby, and according to the department's routine, when the doctor orders to start breastfeeding and feeding the baby, they express their milk and deliver it to the neonatal intensive care unit.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi Hospital

Full name of responsible person

Elham Rohani

Street address

Ferdous Garden Station, Molvi Street

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Tehran

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1168743514

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akbarabadihosp@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kazem mousavizade

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Fifth floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway between Chamran and Sheikh Fazlullah

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Seyedeh saeedeh Mousavi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing and Midwifery., Rashid Yasimi Street., above Vanak Square., Valiasr Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Yes - There is 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

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyedeh saeedeh Mousavi

Position

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Latest degree

Ph.D.

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