Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of foot reflexology on the volume and composition of breast milk inmothers of premature infants admitted to the neonatal intensive care unit

Protocol summary

Study aim
to determine the effect of foot reflexology on the volume and composition of breast milk in mothers of premature babies hospitalized in the neonatal intensive care unit.

Design
Clinical trial with control group, with parallel groups, without blinding, randomized, on 74 mothers, Random Allocation Software was used for randomization.

Settings and conduct
The researcher will refer to the nicu department of Rohani Babol hospital and the samples will be selected according to the entry criteria. They will complete the demographic profile questionnaire. In the intervention group, 20 minutes of foot reflexology is performed daily for seven consecutive days, and sampling is done 30 minutes after reflexology, and reflexology is not performed in the control group. In both groups, milk will be milked from each breast for 15 minutes with the presence of the researcher.

Participants/Inclusion and exclusion criteria
The inclusion criteria include the mother's desire to participate in the research, the intrauterine age of the baby between 28 and 34 weeks, a written doctor's order based on the mother's permissibility of breastfeeding, and the exclusion criteria include stopping breastfeeding due to the clinical conditions of the newborns, the discharge of the baby during Intervention, death of the baby, absence of the mother even for one day during the seven days of the intervention, mothers who have postpartum depression.

Intervention groups
In the intervention group, 20 minutes of foot reflexology is performed daily for seven consecutive days, and reflexology is not performed in the control group.

Main outcome variables
Breast milk volume, breast milk cholesterol, breast milk triglycerides, breast milk albumin, breast milk total protein, breast milk calcium

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221220056872N1**
Registration date: **2023-01-22, 1401/11/02**
Registration timing: **prospective**

Last update: **2023-01-22, 1401/11/02**
Update count: **0**

Registration date
2023-01-22, 1401/11/02

Registrant information

Name
Fatemeh Norozi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-01, 1401/11/12

Expected recruitment end date
2024-02-01, 1402/11/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of foot reflexology on the volume and composition of breast milk inmothers of premature infants admitted to the neonatal intensive care unit

Public title
The effect of foot reflexology on the volume and composition of breast milk inmothers of premature infants admitted to the neonatal intensive care unit

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Mother's willingness to participate in the research Willingness to breastfeed Intrauterine age of the baby 28 to 34 weeks 8- Written order Written order The doctor is based on the permissibility of breastfeeding by the mother The mother must be primiparous, that is, she does not have a previous pregnancy that even leads to abortion

Exclusion criteria:
Cessation of breastfeeding due to the clinical conditions of the infants Discharge of the infant during the intervention Death of the infant Mother's unwillingness to continue participating in the study Absence of the mother even for one day during the seven days of the intervention Mothers with postpartum depression Having skin problems on the mother's foot such as an injury, wound or tumor or mass on the mother's foot to perform reflexology Consumption of milk-enhancing compounds, cigarettes and drugs or anticonvulsant and antipsychotic drugs by the mother Mother suffering from diseases that prohibit breastfeeding Use of contraceptive methods effective on breastfeeding The use of mothers who have therapeutic diets and vegetables

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
People will be included in the study if they are eligible based on the entry criteria and after obtaining written informed consent. Due to the fact that the subjects of the study do not enter the study at the same time, and the researchers cannot predict in advance which group each person who enters the study will belong to. To allocate the target group to one of the two study groups (two groups A and B), block randomization method with six blocks will be used. Then the participants will be assigned to one of two groups 1-control 2-intervention according to the block randomization protocol (produced by Random Allocation Software) with a ratio of 1:1:1, in a way that the researcher cannot predict. In which intervention group is the next person placed? Concealment of random allocation refers to the method used to perform a random sequence on the participants in the study, so that the assigned group is not known before the allocation of the individual. Without hiding the random sequence, there is a possibility of revealing the random sequence, which ultimately weakens the randomization process. Therefore, it is necessary to make a decision to accept or reject participation in the study first and complete the informed consent form and then the participants are assigned to each of the groups. Different methods can be used to hide random allocation. In this study, the method of sealed opaque envelopes with a random sequence will be used. Based on the sample size of this research, a number of opaque envelopes (in order to make the contents of the envelopes unclear) were prepared and each random sequence was created. It is recorded on a card and the cards are placed in the envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the allocated group of that participant will be revealed. More about this source textSource text required for additional translation information Send feedbackSide panels

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 Babol University of Medica l Science

Street address
Department of Nursing, Faculty of Nursing and Midwifery,Babol University of Medical Sciences,Ganj Afroz Road,Babol,Mazandaran

City
Babol

Province
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Postal code
47176-47745

Approval date

2022-12-12, 1401/09/21

Ethics committee reference number

IR.MUBABOL.REC.1401.132

Health conditions studied

1

Description of health condition studied

Breast feeding

ICD-10 code

P92

ICD-10 code description

Feeding problems of newborn

2

Description of health condition studied

Breastfeeding status of mothers

ICD-10 code

O92.5

ICD-10 code description

Suppressed lactation

Primary outcomes

1

Description

Breast milk volume

Timepoint

At the beginning of the study and on the seventh day after the reflexology intervention

Method of measurement

Expressed milk is measured in milliliters in a graduated container.

Secondary outcomes

1

Description

total protein and albumin in breast milk

Timepoint

At the beginning of the study and on the seventh day after the reflexology intervention

Method of measurement

Biochemical index of milk total protein and albumin with a spectrophotometric device made in England model (Unico 9344) with the accuracy of mg/dL, for all samples centrifuged by Clement device (2000 available in the laboratory) total protein and albumin of breast milk It will be recorded based on standard registration instructions and based on mg/dL.

2

Description

fat (cholesterol and triglyceride) in breast milk

Timepoint

At the beginning of the study and on the seventh day after the reflexology intervention

Method of measurement

Biochemical index of milk cholesterol and triglycerides with spectrophotometric device made in England model (Unico 9344) with the accuracy of mg/dL, for all samples centrifuged by Clement device (2000 available in the laboratory) breast milk cholesterol and triglycerides It will be recorded based on standard registration instructions and based on mg/dL.

3

Description

calcium in breast milk

Timepoint

At the beginning of the study and on the seventh day after the reflexology intervention

Method of measurement

Biochemical index of milk calcium with a spectrophotometric device made in England, model (Unico 9344) with the accuracy of mg/dL, for all samples centrifuged by the Clement device (2000 available in the laboratory) of breast milk calcium based on standard registration instructions and based on It will be recorded on a mg/dL basis.

Intervention groups

1

Description

Intervention group: Foot reflexology includes general reflex (preparation, heating and stimulation) and special reflex (massage of pituitary, breast and solar points) for 20 minutes for both legs and 10 minutes for each leg during seven consecutive days. Seven sessions are held daily. 30 minutes after the end of reflexology, milking starts from each breast for 15 minutes.

Category

Other

2

Description

Control group: The control group are mothers who will only be taught routine breastfeeding by the researcher (Master's student). Out of 37 mothers of premature babies in the first group (control group), sampling is done around 11:30. Milk is expressed from each breast for 15 minutes by an electric milking machine in the presence of a researcher (Master's student) and measured in milliliters in a graduated container, and the volume of milk is recorded with the mother's name, baby's name, time, day and date of milking. .

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran, Babol, Ayatollah Rouhani Hospital

Full name of responsible person
Dr. Asghar Molazadeh

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Ayat Rohani Hospital, Keshavarz Blvd, Babol, Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Fatemeh Norouzi Nodehi

Position
Nursing master's student in neonatal special care

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Department of Nursing, Faculty of Nursing and Midwifery,Babol University of Medical Sciences,Ganj Afroz Road,Babol,Mazandaran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Teaching faculty of Babol University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Norouzi Nodehi

Position

Nursing master's student in neonatal special care

Latest degree

Bachelor

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable