Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of reflexology on breast milk of women with premature hospitalized newborns: a randomized control trial

Protocol summary

Summary

The purpose of this trial is to determine the effect of reflexology on breast milk of women with preterm infants. 74 lactating women with preterm infants aged 7-54 days hospitalized in the Alzahra or Taleganie hospitals-Tabriz who have inadequate milk supply were be randomly assigned into two treatment and control groups through stratified [according to recruitment place, multiple or singleton, and infant age (two groups of 7-30 and 31-54)] block randomization. Sequentially numbered opaque sealed envelopes, including a piece of paper with group name written on it, will be used to conceal the allocation sequence. The reflexology will be used on the feet, 10 minutes massage on each foot, once a day for 7 days. The massage will be done on breast, pituitary and solar plexus points in the intervention group and on the shoulder, sciatica and eye points in the control group by the researcher on the first, fourth and seventh days and by the women on the second, third, fifth and sixth days. The researcher will educate the women how to do the massage on the first day and massage will be done under supervision of the researcher on the second day. The main outcomes are: The volume of milk expressed using the electric pump milk by the researcher's help (2 hours after the last feeding and at least half an hour after the massage) and volume of 24 hours expressed breast milk reported on the recording table by the women. The outcomes were measured on the first, fourth and seventh days of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501073706N24**
Registration date: **2015-03-05, 1393/12/14**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2015-03-05, 1393/12/14

Registrant information

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Sakineh Mohammad-Alizadeh-Charandabi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Research deputy- Tabriz University of Medical Sciences

Expected recruitment start date

2015-03-06, 1393/12/15

Expected recruitment end date

2015-09-06, 1394/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of reflexology on breast milk of women with premature hospitalized newborns: a randomized control trial

Public title

The effect of reflexology on breast milk of women with premature hospitalized newborns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: lactating women who have a singleton or twin preterm infant (s) (gestational age of 28.0 to 37.0 weeks) aged 7-60 days hospitalized at the neonatal unit or neonatal intensive care unit; have willing to continue breastfeeding; have 30% or more decreased milk supply compared to the peak volume (based on maternal account) or have inability to provide adequate breast milk to meet infant nutritional needs and a neonatologist confirms the insufficient milk production; have permanent or temporary stay at the hospital during the seven days of intervention. Exclusion criteria: metabolic diseases in the infant (s); infection or sore of woman's feet; chronic systemic illness of the woman; inability to fill up the self-administered questionnaire; no Iranian nationality; occurrence of severe psychological problems for the woman such as death of a close relative in the previous 3 months; and intention to start using a drug which may have an effect on the milk production (e.g. metoclopramide, domperidone) or change dose of the drugs in the next 15 days

Age

From **18 years** old to **40 years** old

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

Blinding (investigator's opinion)

Double 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 Tabriz University of Medical Sciences

Street address

Research Deputy, 3rd floor, Centeral building No 2 , Tabriz University of Medical Sciences, Golgasht st., Tabriz, East Azarbaijan

City

Tabriz

Postal code

Iran

Approval date

2015-02-01, 1393/11/12

Ethics committee reference number

93159

Health conditions studied

1

Description of health condition studied

Breast feeding

ICD-10 code

P92

ICD-10 code description

Feeding problems of newborn

Primary outcomes

1

Description

The volume of milk expressed 2 hours after the last expression and at least half an hour after the massage

Timepoint

Before intervention - on the first, fourth and seventh days of intervention

Method of measurement

Squeezing through the electric pump

2

Description

volume of breast milk expressed during 24 hours

Timepoint

Before intervention- on the first, fourth and seventh days of intervention

Method of measurement

recording on the diary by the women

Secondary outcomes

1

Description

volume of breast milk substitutions given to the infant during 24 hours

Timepoint

Before intervention, on the first, fourth, and seventh days intervention

Method of measurement

using nursing report

2

Description

infant weight gain

Timepoint

before intervention- on the first, fourth and seventh intervention days

Method of measurement

newborn weighting scale with a precision of one gram

3

Description
The infant's heart rate
Timepoint
before intervention, خn the first, fourth and seventh intervention days
Method of measurement
Pulse oximeter

4

Description
Infant oxygen saturation
Timepoint
before intervention, on the first, fourth, seventh intervention days
Method of measurement
Pulse oximeter

5

Description
Depression score of the women
Timepoint
Before intervention, the seventh day of intervention
Method of measurement
Through self-report questionnaire DASS

6

Description
Anxiety score of the women
Timepoint
Before intervention, the seventh day of intervention
Method of measurement
از طریق پرسشنامه خود گزارشی DASS

7

Description
stress score of the women
Timepoint
Before intervention, the seventh day of intervention
Method of measurement
Through self-report questionnaire DASS

8

Description
The proportion of infant feeding with expressed breast milk
Timepoint
seventh day of intervention
Method of measurement
The women report table and nursing reports in the infant record

9

Description
exclusive breastfeeding
Timepoint
seventh day of Intervention
Method of measurement
Nursing report and woman report

10

Description
woman satisfaction of the intervention
Timepoint
seventh day of intervention
Method of measurement
woman report

11

Description
woman satisfaction from breastfeeding
Timepoint
the seventh day of Intervention, Seven days after end of intervention
Method of measurement
woman report

12

Description
occurrence of adverse events
Timepoint
During the study
Method of measurement
woman report

Intervention groups

1

Description
Intervention group: reflexology on the breast, solar plexus and pituitary points on the feet for 20 minutes (10 minutes on each foot), once a day for seven days
Category
Rehabilitation

2

Description
control group: reflexology on the eye, shoulder and back points of feet for 20 minutes (10 minutes for each foot) once a day for seven days
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Parisa Mirzaee
Street address
Crossroads Baghshmal, 17 Shahrivar Street, Tabriz

City
Tabriz

2

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Parisa Mirzaee
Street address
Rah Ahan, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research deputy of Tabriz University of Medical Sciences
Full name of responsible person
Mohammad-Reza Rashidi
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Research Deputy, 3rd floor,Centeral building No 2 , Tabriz University of Medical Sciences, Golgasht st., Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research deputy of Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty