

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

alizades@tbzmed.ac.ir

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, Central 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, on 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

DASS از طریق پرسشنامه خود گزارشی

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

Street address

Research Deputy, 3rd floor, Central 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

Contact

Name of organization / entity

Tabriz University of Medical Sciences, Nursing &
Midwifery Faculty

Full name of responsible person

Parisa Mirzaee

Position

MSc student in Midwifery

Other areas of specialty/work

Street address

Nursing & Midwifery Faculty, South Shariati Street

City

Tabriz

Postal code

Iran

Phone

+98 41 3544 6210

Fax

Email

yoosefe.zahra@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences, Nursing &
Midwifery Faculty

Full name of responsible person

Sakineh Mohammad-Alizadeh Charandabi

Position

PhD of Reproductive Health

Other areas of specialty/work

Street address

Faculty of Nursing & Midwifery, South Shariati Street

City

Tabriz

Postal code

Iran

Phone

+98 41 3479 6770

Fax

Email

alizades@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences, Nursing &
Midwifery Faculty

Full name of responsible person

Sakineh Mohammad-Alizadeh Charandabi

Position

PhD of Reproductive Health

Other areas of specialty/work

Street address

Faculty of Nursing & Midwifery, South Shariati Street

City

Tabriz

Postal code

Iran

Phone

+98 41 3479 6770

Fax

Email

alizadas@gmail.com

Web page address

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