

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of foot reflexology on milk production in mothers with premature neonates

Protocol summary

Summary

The purpose of this trial is to determine the effect of reflexology on milk production in mothers with premature neonates. 45 lactating women with preterm infants aged 4-7 days hospitalized in the Shohada Hospitals -Quchan who were randomly assigned into three treatment and placebo and control groups. The reflexology will be used on the feet, 10 minutes massage on each foot, once a day for 3 days. The massage will be done on breast, pituitary and solar plexus points in the intervention group and on the leg in the placebo and the control group any massage by the researcher on the first and three days. The main outcomes are: The volume of milk expressed using the electric pump milk by the researcher's help (2 hours after the last Expressing 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 and three days of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112425232N1**

Registration date: **2016-01-07, 1394/10/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-07, 1394/10/17

Registrant information

Name

Narges Derakhshan

Name of organization / entity

Gonabab University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 5027

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Recruitment status

Recruitment complete

Funding source

Research deputy- Gonabad University of Medical Sciences.

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-07-20, 1395/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on milk production in mothers with premature neonates

Public title

feeding problems of Premature Infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: lactating women who have a singleton or twin preterm infant (s) (gestational age of 28 to 34 weeks) aged 4-7 days hospitalized at the neonatal intensive care unit; Have neonates are breast-fed by nasogastric tube; Have willing to continue breastfeeding; Mother's have not disease affecting milk production (e.g. Nutrition disorders, depression, diabetes, dehydration); Mothers have not chronic diseases (e.g. cardiovascular

disease or psychological disease, deep vein thrombosis and peripheral nerve diseases);The mothers avoiding use of any medication or treatment affecting on breastfeeding in during research; not infection or sore of woman's fee; No problems mammary (breast fissures, congestion, mastitis and breast abscesses); not occurrence of severe psychological problems for the woman such as death of a close relative or job loss).
Exclusion criteria: Unwillingness women to continuation of presence at research; intention to start using a drug which may have an effect on the milk production (e.g. metoclopramide, domperidone); If naonate require of endotracheal intubation and general condition ill.

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: **45**

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**

Gonabad University of Medical Sciences

Street address

KHorasan Razavi, Gonabad, Gonabad University of Medical Sciences

City

Gonabad

Postal code**Approval date**

2015-12-23, 1394/10/02

Ethics committee reference number

IR.GMU.REC.1394.60

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 and three days of intervention

Method of measurement

Squeezing through the electric pump

Secondary outcomes**1****Description**

volume of breast milk expressed during 24 hours

Timepoint

Before intervention- on the firs and three days of intervention

Method of measurement

recording on the diary by the women

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 three days

Category

Prevention

2**Description**

The control group: without action

Category

Prevention

3**Description**

The placebo group: received a gentle massage on the legs for 20 minutes (10 minutes on each foot), once a day for three days

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Narges Derakhshan

Street address

Shohada Hospital, crossroads tarbiat, Quchan

City

Quchan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabab University of Medical Sciences

Full name of responsible person

Dr Mohammadpour Ali, Research and Tecnology
Department of Gonabab University of Medical
Sciences, Pr

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Gonabab University of Medical Sciences

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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

Gonabab 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**

Gonabab University of Medical Sciences

Full name of responsible person

Narges Derakhshan

Position

Graduate Student in Nursing Education, Nursing
children

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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