Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A clinical trial to compare the effectiveness of back and reflexology massage on milk volume of mothers of preterm infants

Protocol summary

Summary

This study will be done with aim to investigate the effectiveness of back massage and reflexology on the volume of milk of preterm infants' mothers admitted to the NICU ward of hospitals affiliated by Isfahan University of Medical Sciences, 2015. This study is a non-blind clinical trial. The study population consists of mothers with 29 _ 33 week premature infants admitted to the NICU wards of Behesti and Al-Zahra hospitals. Inclusion criterion is undergoing cesarean and main exclusion criterion is using drug affecting lactation. In this study, 75 eligible mothers will be selected and will randomly be assigned in to 3 groups (2 experimental and 1 control groups). Before the intervention, all mothers will be asked to milk themselves by milkmaid for 15 minutes and the volume of milk will be measured in all of them. In the first study group reflexology will be done for each leg separately for 20 minutes, daily for 6 days. In the second experimental group, back massage of simple slow stroke type will be done with open fingers on either sides of the spinal column and shoulders for ten minutes for 6 consecutive days. The control group did not receive any massage. At the end of the study, mothers will be asked to milk themselves by milkmaids and the volume of milk will be measured again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120126153N3**
Registration date: **2017-04-01, 1396/01/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-01, 1396/01/12

Registrant information

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Atena Mohammadpour
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Esfahan University of Medical Sciences

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2017-05-10, 1396/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of back and reflexology massage on milk volume of mothers of preterm infants

Public title

Compare the effects of two massage method on milk volume of mothers of preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Mothers with29 _ 36 weeks premature infants; The absence of any damage, ulcers and tumors

in massage area in the back and legs, passing three days from the childbearing; undergoing cesarean; No history of back massage and reflexology. Exclusion criteria: using drug affecting the lactation including antibiotics, anticonvulsants and antipsychotics.

Age
From **7 months** old to **9 months** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization will be done through drawing a card using encoded on the cards 1,2,3. Patients randomly select one of the cards and their group will be set according to the number they choose

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee , Esfahan University of Medical Sciences

Street address
Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, Hezarjarib street

City
Esfahan

Postal code

Approval date
2016-09-11, 1395/06/21

Ethics committee reference number
IR.MUI.REC.1394.3.462

Health conditions studied

1

Description of health condition studied
mothers' Lactation

ICD-10 code
O92.5

ICD-10 code description
Suppressed lactation

2

Description of health condition studied
preterm infant

ICD-10 code
P07.3

ICD-10 code description
Other preterm infants

Primary outcomes

1

Description
Milk volume

Timepoint
Baseline, the end of the study

Method of measurement
Inserted milk jugs

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group reflexology will be done for each leg separately for 20 minutes, totally 40 minutes(15 minutes general reflexes and 5 minutes specialized reflexes) daily during 6 sessions.

Category
Treatment - Other

2

Description
Intervention group 2: In this group back massage of simple slow stroke type with open fingers on either side of the spine and shoulder will be done for ten minutes for 6 days.

Category
Treatment - Other

3

Description
The control group will not receive any massage

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Atena Mohammadpour
Street address
Shahid Beheshti Hospital, Motahari street, Pol Felezi
City
Esfahan

2

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Atena Mohammadpour
Street address
Sefeh Boulevard
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Esfahan University of Medical Sciences
Full name of responsible person
Akram Mazaheri
Street address
Vice Chancellor for Research Affairs, Esfahan University of Medical Sciences, Hezarjarib Street
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Esfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Esfahan 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
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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