

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of two methods of ring band & nipple massage on successes of breastfeeding among mothers with nipple problems

Protocol summary

Summary

Objective: Comparing effectiveness of two methods of ring band & nipple massage on successful breastfeeding among mothers with nipple problems. Design: Randomized controlled clinical trial. Method: It will be conducted in hospitals of Tabriz (Al- Zahra and Taleghani). The qualified individuals will randomly be allocated to three groups of 33 persons with blocks of 6 and 9. One of the members of research team who is not involved in sample selection, will determine random allocation sequence using the computer program. The closed opaque envelopes will be scored respectively and used to hide the allocation. Intervention will begin 0.5 and 3 hours after vaginal delivery and cesarean section respectively, after mothers' physical stability. Mothers in the intervention groups will receive: 1 (ring band at the base of nipple which obtained from condom brim), 2 (massage of nipple or Hoffman massage) and 3 as control group (receive nipple's shield as the routine method of maternity ward). The variables of main outcome: The number of infants' breast feeding during 1, 7 and 15 days, the ratio of infants' bounding and the frequency of adverse events in mother and infants will be measured at groups of study during 1 and 15 days after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512078170N9**

Registration date: **2016-03-13, 1394/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-13, 1394/12/23

Registrant information

Name

Jamileh Malakouti

Name of organization / entity

Nursing Faculty

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-02-22, 1394/12/03

Expected recruitment end date

2016-10-01, 1395/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of two methods of ring band & nipple massage on successes of breastfeeding among mothers with nipple problems

Public title

Successful breastfeeding with inverted nipples

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Aged between 18-40; willingness of women to participate at study; ability to read and write Persian; infant birth weight between 2000 and 4000 gr;

mothers with flat or inverted nipple problem; phone number for follow-up Exclusion criteria:Using pumps; caps or any other devices to facilitate breastfeeding; mothers' infants with physiological; anatomical and other abnormalities no able to feed orally; history of physical and mental illness of the mother (epilepsy; gastrointestinal disorders; cardiovascular; kidney); having stressful accidents 1 month ago such as divorce; death of family members; using effective drugs during breastfeeding (to increase and decrease milk and hormones); presence of a disease or disorder affecting the attachment of the baby on mother

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Tabriz University of Medical Sciences

Street address

Azadi st; Golgasht Street ; Tabriz University of Medical Sciences Research & Technology

City

Tabriz

Postal code

51665118

Approval date

2015-11-26, 1394/09/05

Ethics committee reference number

rec.1394/779

Health conditions studied

1

Description of health condition studied

Breast-feeding problems

ICD-10 code

92.5

ICD-10 code description

Neonatal difficulty in feeding at breast

Primary outcomes

1

Description

The number of infants' breast-feeding

Timepoint

1, 7, 15

Method of measurement

Device for weight gain

2

Description

Comparing the number of infants' breast-feeding during 1, 7 and 15 days at massage group

Timepoint

1, 7 and 15

Method of measurement

Calculating the number of infants' breast-feeding and device for weight gain

3

Description

Comparing the number of infants breast-feeding during 1, 7 and 15 days at 3 groups

Timepoint

1, 7, 15

Method of measurement

Calculating the number of infants' breast-feeding and device for weight gain

Secondary outcomes

1

Description

Mother-infant bonding

Timepoint

Day 1 and 15 after intervention

Method of measurement

Maternal-fetal bonding scale

2

Description

Determining the frequency of adverse events in mother and infant at groups of study

Timepoint

1-14 after intervention

Method of measurement

Self- designed check List

Intervention groups

1

Description

The first group of intervention will receive ring bond at the base of nipple which cut from condom brim for successful breast-feeding

Category

Prevention

2

Description

The second group of intervention will receive massage of nipple or Hoffman massage for successful breast-feeding

Category

Prevention

3

Description

The control group will receive nipple's shield as the routine method of maternity ward for successful breast-feeding

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Maryam Kahfroshan

Street address

South Artesh street

City

Tabriz

2

Recruitment center

Name of recruitment center

Shahid Khanly

Full name of responsible person

Afkham Fazel Fard

Street address

Shahid Khanly: Health Center of Supporting Breast-Feeding Mothers; Beheshti st

City

Tabriz

3

Recruitment center

Name of recruitment center

Talegani Hospital

Full name of responsible person

Shakiba Poor Asad

Street address

Rah Ahan st

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Rashidi

Street address

Number 2; Third floor; Golgasht Street; Azadi Avenue; Central Construction; Research department; Tabriz Medical Science University; Tabriz

City

Tabriz

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, 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

Faculty of Nursing and Midwifery, Tabriz Medical Science University

Full name of responsible person

Jamileh Malakouti

Position

Academic member; Faculty of Nursing and Midwifery; Tabriz

Other areas of specialty/work

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Person responsible for scientific inquiries

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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