

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The Effect of Chamomile Ointment on Treatment of Nipple Fissure in Breast Feeding Mothers

Protocol summary

Study aim

Determination of the effect of chamomile ointment on treatment of Nipple fissure in breastfeeding mothers

Design

Clinical trials with controlled, randomized, and single blind

Settings and conduct

Sampling is done in health centers. In the absence of sensitivity, the ointment of chamomile & lanolin is used 3 times a day after lactation; the treatment is conducted for 7 days. On the 3rd and 7th days, the mother refer to be examined after the intervention, and the effect of the intervention is measured by using Storr scale and the pain scale ruler

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years; nipple fissure with a 1-4 Storr score; Singleton birth; The term baby; The natural weight of the baby (2500-4000); Infant without any congenital malformation of palate, jaw and face and short frenulum; Exclusive breastfeeding; Moms with average and good breastfeeding scores; lack of nipple abnormalities such as indented nipple and breast or nipple surgery; very small or large breast; Lack of maternal immunodeficiency diseases; diabetes and hypertension; Lack of mother's neurological diseases and depression; Insensitivity to chamomile and lanolin ointments; Non-compliance criteria: Sick and bedridden baby; Mastitis; abscess or puerperal fever; Infant's being infected to oral infections; Taking antibiotics, other topical ointment; or analgesics

Intervention groups

Intervention 1: Using chamomile ointment as a fingernail on the nipple fissure and areola 3 times a day for one week during the study + Training the correct lactation technique
Intervention 2: Interventions 1: Using lanolin ointment as a fingernail on the nipple fissure and areola 3 times a day for one week during the study + Training the correct lactation technique

Main outcome variables

The severity of breast fissure and the amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180127038528N1**

Registration date: **2018-07-09, 1397/04/18**

Registration timing: **retrospective**

Last update: **2018-07-09, 1397/04/18**

Update count: **0**

Registration date

2018-07-09, 1397/04/18

Registrant information

Name

shaghayegh Dehghan nayeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3610 8022

Email address

dehghannayeri.sh@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Chamomile Ointment on Treatment of Nipple Fissure in Breast Feeding Mothers

Public title

"Effect of Chamomile Ointment in Treatment of Nipple Fissure"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

At least 18 years old Nipple fissure with 1-4 score for Store Single delivery The term baby The natural weight of the baby (2500-4000 gr) Infant without congenital malformation; plate, jaw and face and short fernaloma Exclusive breastfeeding Absence of nipple abnormalities such as nipple and breast or nipple surgery; very small or large breast Lack of maternal immunodeficiency diseases; diabetes and hypertension Lack of mother's neurological diseases and depression Insensitivity to chamomile and lanolin ointments Mothers with a lactation position grade score; medium and good

Exclusion criteria:

Sickness and bedridden baby Mastitis; abscess or puerperal fever Infant's being infected to oral infections Taking antibiotics, other topical ointment; or analgesics

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Qualified patients will be randomly assigned to one of the two groups of lanolin ointment and chamomile. To randomize the block method Randomized block permuted with 4 blocks. According to volume The sample of which 106 is set, the 4th block using the site (www.sealedenvelope.com) will be. In order to apply the concealment in the randomization process, the unique codes on the ointment line The code will be used by the software.

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher (midwife) is not informed of the type of drug used in the studied groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2017-10-03, 1396/07/11

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9413373002

Health conditions studied

1

Description of health condition studied

Nipple fissure

ICD-10 code

N64.0

ICD-10 code description

Fissure and fistula of nipple

Primary outcomes

1

Description

Nipple pain

Timepoint

Before intervention ,3 and 7 days after intervention

Method of measurement

Visual Analogue scale

2

Description

Nipple fissure

Timepoint

Before intervention ,3 and 7 days after intervention

Method of measurement

Storr scale

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, after breastfeeding, chamomile cream will be rubbed 3 times a day for 7 days on the nipple and the areola around it.

Category

Treatment - Drugs

2

Description

In the control group: after breastfeeding Lanolin will be rubbed 3 times a day for 7 days on the nipple and the areola around it.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Selected Health Care Centers in Alborz

Full name of responsible person

Dehghan nayeri shaghayegh

Street address

Amirabad street., Health Center

City

Karaj

Province

Alborz

Postal code

3164838441

Phone

+98 26 3610 8022

Email

Sh.midwife31680@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Malakuti Kazem

Street address

Tehran, Hemat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

PR@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dehghan nayeri shaghayegh

Position

collegian

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

No.4, dehghan nayeri., amir abad Blvd., Garmdare town

City

Karaj

Province

Alborz

Postal code

3164838441

Phone

+98 26 3610 8022

Email

Sh.midwife31680@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kheirkhah masume

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

Street address

Tehran, Hemat Highway next to Milad Tower, Iran
University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

Shivakheirkhah1345@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dehghan nayeri shaghayegh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing & Midwifery, Rashid Yasemi Ave.,
Valiasr Ave.

City

Tehran

Province

Tehran

Postal code

۱۹۹۶۷۱۳۸۸۳

Phone

+98 21 8670 5503

Email

Sh.midwife31680@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available