

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Effect of peppermint water, Alovra jelly and breast milk on the breast fissure at breastfeed women

Protocol summary

Shahid Beheshti University of Medical Science

Summary

This research is a clinical trial at the at the breastfeed women referring to Shahid beheshti university of medical science healthcara centers with research unit criteria. Women after interance in research will divide in three groups. In one group will use peppermnt water, anotherwill use Alovra jelly and third group will use breast milk after breasfeeding on the breast nipple and areol. Then will be camper three groups as pain, discharge and damage of breast nipple in 5 times.

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Scientific title

Effect of peppermint water, Alovra jelly and breast milk on the breast fissure at breastfeed women

Acronym

IRCT registration information

IRCT registration number: **IRCT201206166807N5**

Registration date: **2012-06-30, 1391/04/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-06-30, 1391/04/10

Registrant information

Name

Sedigheh Amir Ali Akbari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2272 9240

Email address

akbarisedd@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Public title

Effect of peppermnt water, Alovra jelly and breast milk on the breast fissure at the breastfeed women referring toShahid beheshti university of medical science healthcare centers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: single pregnancy; no breast abnormality; first pregnancy and term pregnancy.

Exclusion criteria: post partum fever; neonatal mouth infection; breast infection and neonate short fernolom.

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: **150**

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

shahid beheshti university of medical science

Street address

research manager,shahid beheshti university of medical science, near the Taleghani hospital,Tabnak St,Evin, Chamran highway, Tehran

City

Tehran

Postal code

Approval date

2012-03-17, 1390/12/27

Ethics committee reference number

8212-8141-86-1-90

Health conditions studied

1

Description of health condition studied

Breast fissure

ICD-10 code

N61.0

ICD-10 code description

Inflammatory disorders of breast

Primary outcomes

1

Description

Pain

Timepoint

3, 5, 7, 10, 12 and 14 days after delivery

Method of measurement

Mack gil roller

2

Description

Discharge

Timepoint

3, 5, 7, 10, 12 and 14 days after delivery

Method of measurement

Observation

3

Description

Breast nipple damage

Timepoint

3, 5, 7, 10, 12 and 14 days after delivery

Method of measurement

Observation

Secondary outcomes

1

Description

Allergy

Timepoint

3, 5, 7, 10, 12 and 14 days after delivery

Method of measurement

Pirorrtus and irritation assessment

Intervention groups

1

Description

second group: breastfeed women with breast fussier will use 0.5 CC Aloevera jelly after every times breastfeeding on the breast nipple and areola at third day after delivery.Then will be evaluate level of pain , damage and discharge in 5 times(5,7,10,12,14 days after delivery)

Category

Treatment - Drugs

2

Description

third group: breastfeed women with breast fussier will use1 drip breast milk after every times breastfeeding on the breast nipple and areola at third day after delivery.Then will be evaluate level of pain , damage and discharge in 5 times(5,7,10,12,14 days after delivery)

Category

Treatment - Drugs

3

Description

First group: breastfeed women with breast fussier will use4 drip peppermint water after every times breastfeeding on the breast nipple and areola at third day after delivery.Then will be evaluate level of pain , damage and discharge in 5 times(5,7,10,12,14 days after delivery)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh hospital

Full name of responsible person

Seideh Hanieh Aamolhoda

Street address

Mahdieh hospital, fadaeian eslam St, shosh Sq.Tehran

City

Tehran

Faculty of Nursing and Midwifery, Niayesh highway and Valiasr junction,Tehran

City

Tehran

Postal code

Phone

+98 21 8820 2512

Fax

Email

akbarisedd@sbmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fariba Tadaion

Street address

Tehran, Shahid beheshti university of medical science, Tabnak St,Evin, Chamran highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

sedigheh amir ali akbari

Position

Master, Faculty member

Other areas of specialty/work

Street address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

sedigheh amir ali akbari

Position

Master, Faculty member

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Niayesh highway and Valiasr junction,Tehran

City

Tehran

Postal code

Phone

+98 21 8820 2512

Fax

Email

akbarisedd@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

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