

# 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

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Tehran

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**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*