

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Comparison of the effect of mint herbal tea and peppermint cream versus expressed breast milk on treatment of cracked nipple in women during breastfeeding: a randomized controlled trial

#### Protocol summary

##### Summary

Objectives: To compare the effect of mint herbal tea and peppermint cream versus expressed breast milk on treatment of cracked nipple in women during breastfeeding. Design: a double blind randomized clinical trial. Setting and conduct: The eligible women with cracked nipple who will refer to Hamadan Health Centers during the study period will be enrolled into the trial. Inclusion criteria: breastfeeding; cracked nipple; age of 15 to 40 years; Hamadan resident; literate; having a phone line for communication; having a term, singleton, healthy newborn weighting between 2500 to 4000 gr; exclusive breast feeding. Exclusion criteria: oral, palate, jaw or facial abnormalities; addiction and psychiatric problems; breast infection or inflammation; using antibiotic. Intervention group: (a) compresses of mint tea bag on nipple for 15 min 4 times a day for 2 weeks; (b) mint cream 1 ml on nipple for 15 min 4 times a day for 2 weeks. Control group: mother's breast milk 1 ml on nipple for 15 min 4 times a day for 2 weeks Primary outcome: improvement of cracked nipple on 4, 8, and 14 days from beginning of the treatment through physical examination. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201611039014N131**  
Registration date: **2016-11-18, 1395/08/28**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-11-18, 1395/08/28

#### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

#### Expected recruitment start date

2016-12-03, 1395/09/13

#### Expected recruitment end date

2017-05-03, 1396/02/13

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effect of mint herbal tea and peppermint cream versus expressed breast milk on treatment of cracked nipple in women during breastfeeding: a randomized controlled trial

#### Public title

Comparison of the effect of mint herbal tea and

peppermint cream versus expressed breast milk on treatment of cracked nipple in women during breastfeeding

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: breastfeeding; cracked nipple; age of 15 to 40 years; Hamadan resident; literate; having a phone line for communication; having a term, singleton, healthy newborn weighting between 2500 to 4000 gr; exclusive breast feeding. Exclusion criteria: oral, palate, jaw or facial abnormalities; addiction and psychiatric problems; breast infection or inflammation; using antibiotic.

## Age

From **15 years** old to **40 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **216**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

##### Postal code

6517838695

#### Approval date

2016-10-29, 1395/08/08

#### Ethics committee reference number

IR.UMSHA.REC.1395.332

## Health conditions studied

### 1

#### Description of health condition studied

cracked nipple

#### ICD-10 code

N64.0

#### ICD-10 code description

Fissure and fistula of nipple

## Primary outcomes

### 1

#### Description

improvement of cracked nipple

#### Timepoint

on 4, 8, and 14 days from beginning of the treatment

#### Method of measurement

through physical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: compresses of mint tea bag on nipple for 15 min 4 times a day for 2 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: mint cream 1 ml on nipple for 15 min 4 times a day for 2 weeks

#### Category

Treatment - Drugs

### 3

#### Description

Control group: mother's breast milk 1 ml on nipple for 15 min 4 times a day for 2 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hamadan Heath Centers

##### Full name of responsible person

Tayebeh Gharaknani

**Street address**

School of Nursing and Midwifery, Hamadan University  
of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**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 the Technology, Hamadan  
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**

School of Nursing and Midwifery

**Full name of responsible person**

Tayebeh Gharaknani

**Position**

Midwife

**Other areas of specialty/work**

**Street address**

School of Nursing and Midwifery, Hamadan University  
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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

Dr Zahra Massomi

**Position**

Health Fertility Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

**Other areas of specialty/work**

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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*