

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

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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
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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

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Person responsible for updating data

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Name of organization / entity

Department of Epidemiology

Full name of responsible person

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Position

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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