

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of thyme tea bag and chamomile tea bag versus milked milk on nipple crack's repair during breastfeeding period: a randomized controlled trial

Protocol summary

Study aim

To assess the effect of tea bag (thyme) and tea bag (chamomile) versus milked milk on nipple crack's repair during breastfeeding period

Design

This is a randomized clinical trial with control group, in which 108 eligible patients will be randomly assigned through block randomization to three intervention groups (receiving thyme tea bag or chamomile tea bag) and control group (receiving milked milk).

Settings and conduct

This study will be performed in the Comprehensive Health Centers in Hamadan city. The patients will be randomly assigned to the intervention and control groups through block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 45 years, Lactating women with nipple crack; A full-term, singleton, healthy baby with a minimum weight of 2,500 to 4,000 grams; Exclusive breastfeeding; Exclusion criteria: A baby with any abnormality in the mouth, palate, jaw and face; Nipple abnormality or history of previous nipple surgery; Mastitis, abscess or fungal infection of the breast;

Intervention groups

Intervention group 1: Thyme tea bag on the nipple for 15 minutes 4 times a day for 14 days. Intervention group 2: Chamomile tea bag on the nipple for 15 minutes 4 times a day for 14 days. Control group: Rubbing maternal milk on the nipple for 15 minutes 4 times a day for 14 days

Main outcome variables

Intensity of nipple crack

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N413**

Registration date: **2021-12-18, 1400/09/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-18, 1400/09/27**

Update count: **0**

Registration date

2021-12-18, 1400/09/27

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-16, 1400/09/25

Expected recruitment end date

2023-09-04, 1402/06/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of thyme tea bag and chamomile tea bag versus milked milk on nipple crack's repair during breastfeeding period: a randomized controlled trial		Ethics Committee of Hamadan University of Medical Sciences	
Public title		Street address	
Comparison of the effect of thyme tea bag and chamomile tea bag versus milked milk on nipple crack's repair during breastfeeding period		Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave	
Purpose		City	
Treatment		Hamadan	
Inclusion/Exclusion criteria		Province	
Inclusion criteria:		Hamadan	
Age of 18 to 45 years Lactating women with nipple crack A full-term, singleton, healthy baby with a minimum weight of 2,500 to 4,000 grams Exclusive breastfeeding		Postal code	
Exclusion criteria:		6517838695	
A baby with any abnormality in the mouth, palate, jaw and face Nipple abnormality or history of previous nipple surgery Mastitis, abscess or fungal infection of the breast		Approval date	
Age		2021-10-30, 1400/08/08	
From 18 years old to 45 years old		Ethics committee reference number	
Gender		IR.UMSHA.REC.1400.606	
Female		Health conditions studied	
Phase		<u>1</u>	
N/A		Description of health condition studied	
Groups that have been masked		Nipple crack	
No information		ICD-10 code	
Sample size		N64.0	
Target sample size: 108		ICD-10 code description	
Randomization (investigator's opinion)		Fissure and fistula of nipple	
Randomized		Primary outcomes	
Randomization description		<u>1</u>	
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.		Description	
Blinding (investigator's opinion)		Intensity of nipple crack	
Not blinded		Timepoint	
Blinding description		Before the intervention and on days 4, 8 and 14 after the intervention	
Placebo		Method of measurement	
Not used		Using Storr questionnaire	
Assignment		Secondary outcomes	
Parallel		empty	
Other design features		Intervention groups	
Secondary Ids		<u>1</u>	
empty		Description	
Ethics committees		Intervention group 1: Thyme tea bag on the nipple for 15 minutes 4 times a day for 14 days	
<u>1</u>		Category	
Ethics committee		Treatment - Other	
Name of ethics committee		<u>2</u>	
		Description	
		Intervention group 2: Chamomile tea bag on the nipple for 15 minutes 4 times a day for 14 days	
		Category	
		Treatment - Other	

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Description

Control group: Rubbing milked milk on the nipple for 15 minutes 4 times a day for 14 days

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers in Hamadan city

Full name of responsible person

Arezoo Shayan

Street address

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

City

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Province

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6517838695

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Arezoo Shayan

Position

Master of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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

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Full name of responsible person

Dr. Jalal Poorolajal

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Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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