

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison the Local Effect of Achillea Millefolium and Breast Milk on the Improvement of cracked Nipple in Breast Feeding Women

Protocol summary

Study aim

Determining the Effect of Local Form Achillea Millefolium on the Improvement of Nipple Fissure in Lactating Women Referring to Comprehensive Health Centers in Hamadan City in 2018

Design

Clinical trials with control group, randomization On 84 breast-fed women with Nipple Fissure is performed

Settings and conduct

Women with nipple fissure symptoms referring to comprehensive health centers in 2018 ; If they have conditions for entering the study, they will be included in the study

Participants/Inclusion and exclusion criteria

All lactating women with nipple fissure Exclusive nutrition with breast feeding Lack of infant to any abnormalities in the mouth and palate and jaw Missing mother to any type of nipple abnormality or previous nipple surgery Mother dose not use any treatment until a week before the study begins If using a pacifier or milk glass Taking antibiotic by mother

Intervention groups

Intervention group: Achillea Millefolium tea bag is placed 4 times a day for 14 days on nipple Control group: A portion of breast milk is placed on the nipple after each breast feeding

Main outcome variables

Severity of nipple fissure; The amount of pain in the fissure of the breast

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180707040370N1**

Registration date: **2018-08-01, 1397/05/10**

Registration timing: **prospective**

Last update: **2018-08-01, 1397/05/10**

Update count: **0**

Registration date

2018-08-01, 1397/05/10

Registrant information

Name

Ensiyeh Jenabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0496

Email address

e.jenabi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Local Effect of Achillea Millefolium and Breast Milk on the Improvement of cracked Nipple in Breast Feeding Women

Public title

The Local Effect of Achillea Millefolium on the Improvement of cracked Nipple

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All lactating women with cracked nipple Resident of Hamadan Literacy and at least one telephone line for calling Suffering of cracked nipple fissure with a minimum score of two from the Stour scale Has a term new born Single and having a minimum weight between 2500 and 4000 grams The absence of maternal addiction and psychological problem or any type of internal or infectious disease Exclusive nutrition with breast feeding Lack of infant to any abnormalities in the mouth and palate and jaw No having any type of nipple abnormality or previous nipple surgery No using any treatment until a week before the study begins

Exclusion criteria:**Age**

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation of the participants to the groups is performed by method of allocation concealment. In this way, using the random block 4, the allocation sequence is specified. Then, in the sealed envelopes, the intervention name is written in sequential order, and is numbered accordingly.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamadan University of Medical Sciences

Street address

Fahmide Ave., Hamadan University of Medical Sciences

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-06-26, 1397/04/05

Ethics committee reference number

IR.UMSHA.REC.1397.219

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: compresses of Achillea Millefolium tea bag on nipple for 15 min 4 times a day for 2 weeks

Category

Treatment - Drugs

2**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 Health Centers

Full name of responsible person

Sara Abdoli

Street address

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Sara Abdoli
Position
Student
Latest degree

Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

A portion of the information, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Any analysis on the data is pertinent with the source.

From where data/document is obtainable

Hamadan University of Medical Sciences

What processes are involved for a request to access data/document

6 months after printing results

Comments