Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

effects of Purslane Cream on the BreastFissure in Lactating Women: A Clinical Trial

Protocol summary

Study aim
effects of purslane on the nipple fissure
Design
A randomized, controlled, double-blind, placebo-controlled clinical trial
Settings and conduct
This study was performed in health centers of Mashhad. Subjects were randomly assigned into two groups of purslane and lanolin cream and received treatment three times a week.
Participants/Inclusion and exclusion criteria
The inclusion criteria were Iranian nationality, the resident of Mashhad, single and termpregnancy, the possibility for a phone call, being literate, exclusive breastfeeding, obtainingthe score of at least 2 from the Store scale.Exclusion CriteriaThe exclusion criteria included maternal nipple abnormalities , known psychological and cardiovascular diseases in mother. abscess an infection of breast in the mother, use of pacifier, milk glass and plastic breast nipple, infant's disease, infant's infection to oral mucosa during the study, mother's infection to infectious diseases, sensitivity to purslane cream and lanolin during use, lack of visits at determined days for anyreason, the mother's use of other treatments such as using milk, or antibiotics during the studyperiod, not using the treatment for one day or less than three times a day,
Intervention groups
in groups purslane and lanolin use it on the nipple as amount of a finger, three times a day immediately after breastfeeding, to cover the entire thin layer of the fissure and continue treatment up to seven days.
Main outcome variables
This study was performed in health centers of Mashhad. Subjects were randomly assigned into two groups of purslane and lanolin cream and received treatment three times a week. The pharmacist put the drug in the same and similar package so that the researcher and the research unit were unaware of the type of treatment.

General information

Reason for update
Edit study information according to who criteria
Acronym
IRCT registration information
IRCT registration number: **IRCT2015042421915N1**
Registration date: **2017-01-28, 1395/11/09**
Registration timing: **retrospective**

Last update: **2019-10-16, 1398/07/24**
Update count: **1**
Registration date
2017-01-28, 1395/11/09

Registrant information
Name
Azin Niazi
Name of organization / entity
Mashhad Univercity of Medical Sciences
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Recruitment status
Recruitment complete
Funding source
Mashhad University of Mdical Sciences

Expected recruitment start date
2016-10-08, 1395/07/17
Expected recruitment end date
2016-12-26, 1395/10/06
Actual recruitment start date
2016-10-08, 1395/07/17
Actual recruitment end date
2016-12-26, 1395/10/06
Trial completion date

2017-11-11, 1396/08/20

Scientific title
effects of Purslane Cream on the BreastFissure in Lactating Women: A Clinical Trial

Public title
Purslane Cream on the Breast Fissure

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The inclusion criteria were Iranian nationality, the resident of Mashhad, single and termpregnancy, the possibility for a phone call, being literate, exclusive breastfeeding, obtainingthe score of at least 2 from the Store scale.

Exclusion criteria:
Exclusion CriteriaThe exclusion criteria included maternal nipple abnormalities , known psychological and cardiovascular diseases in mother. Moreover, other exclusion criteria were abscess an infection of breast in the mother, use of pacifier, milk glass and plastic breast nipple, infant's disease, infant's infection to oral mucosa during the study, mother's infection to infectious diseases, sensitivity to purslane cream and lanolin during use, lack of visits at determined days for anyreason, the mother's use of other treatments such as using milk, or antibiotics during the studyperiod, not using the treatment for one day or less than three times a day, and mother's use ofcold or hot compresses

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **86**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In the present study, multi-stage sampling was performed. In the first stage, sampling was done in a class. The classes are the five regions of health centers (1-5) of Mashhad, Iran. They were randomly selected from two classes (center number 3 and 5). The second phase of sampling was randomly carried out according to the ratio of the patients referred to the thyroid clinic of centers 3 and 5. In the third stage, among the lactating women referring to these 4 thyroid clinic centers, firstly, the units of study were selected by inclusion criteria and then placed in two groups of lanolin and purslane creams on the basis of random numbers. Noteworthy, mothers along with their children should be routinely visited by their health centers on the third to fifth day after childbirth to screen and prevent the hypothyroidism and related disorders. In this regard, these centers were selected to provide more access to lactating women during this period. Following the selection, required explanations regarding the research design, the method of research, how to use drugs and the probability of drug allergy were given to them. If they wished to participate in the research, written consent was obtained in order to observe the ethical issues, they were assured about the confidentiality of their information and they can leave the study at any time desired. Using the number cruncher statistical system (NCSS) software, the samples were randomly assigned to one of the two groups of lanolin and purslane cream

Blinding (investigator's opinion)
Double blinded

Blinding description
Drugs were packed by the pharmacist who un-known regarding the process of the study, in the same tubes of 30 grams and was coded (A and B).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice Chancellor for research of Mashhad University of medical sciences

Street address
Mashhad ، Ghoreshi Building ، Daneshgah street

City
Mashhad

Province
Razavi Khorasan

Postal code
6818714818

Approval date
2016-09-18, 1395/06/28

Ethics committee reference number
IR.MUMS.REC.1395.300

Health conditions studied

1

Description of health condition studied
Nipple fissure

ICD-10 code
N64.0

ICD-10 code description
Fissure and fistula of nipple

Primary outcomes

1

Description
Breast Fissure
Timepoint
Before intervention, day 3 and day 8 after intervention
Method of measurement
Using Stour scale

Secondary outcomes

1

Description
The improvement of nipple fissures
Timepoint
Before intervention, day 3 and day 8 after intervention
Method of measurement
Measure the severity of damage, by store

Intervention groups

1

Description
In the intervention group after breastfeeding 1gr purslane cream will be rubbed to the nipple and areola 3 times a day for8 days.control group after breastfeeding 1grlanolin cream will be rubbed to the nipple and areola 3 times a day for8 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Centers In Mashhad
Full name of responsible person
Azin Niazi
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The Doctor's Way
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaqodi
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Mashhad، Ghoreshi Building , Daneshgah street
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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 and Technology Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Azin Niazi
Position
Master of Science University Student of Midwifery
Latest degree
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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

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Person responsible for updating data

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Azin Niazi

Position

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Promising effects of Purslane Cream on the Breast Fissure in Lactating Women: A Clinical Trial

When the data will become available and for how long

2018

To whom data/document is available

student midwife

Under which criteria data/document could be used

systematic review

From where data/document is obtainable

azin_niazi65@yahoo.com

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

Articles published in this field will be sent to the applicant.

Comments

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