

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Scrophularia Striata Plant on Breast Fissure of Lactating women

Protocol summary

Study aim

Determine the Effect of Scrophularia Striata on Breast Fissure of Lactating Women

Design

Clinical trial with two intervention group(Scrophularia Striata plant and Lanolin),Double blind,randomized, random sampling, randomly assigned to two groups of Scrophularia Striata and lanolin using NCSS software,the sample size is 80 people, this is a phase 3 clinical trial.

Settings and conduct

The location of this intervention is Ommolbanin and Imam Reza Hospital city of Mashhad. In this study, each intervention group used Scrophularia striata cream on nipple and Areola after feeding Three times a day for 7 days. Mothers in control group apply Lanolin on nipple and areola after each feeding for 7 days .

Participants/Inclusion and exclusion criteria

Inclusion Criteria: single-child delivery; have a term and healthy baby; exclusive breastfeeding; birth weight of more than 2500 grams and less than 4,000 grams. Withdraw criteria:History of identified mental illnesses in mother, History of allergy to Scrophularia Striata and Lanolin.

Intervention groups

The intervention groups consisted of two groups of 40 each, the first group was Scrophularia striata and the second group is the control and received the Lanolin.

Main outcome variables

Reduction of nipple pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190315043059N1**

Registration date: **2019-03-31, 1398/01/11**

Registration timing: **prospective**

Last update: **2019-08-04, 1398/05/13**

Update count: **1**

Registration date

2019-03-31, 1398/01/11

Registrant information

Name

Hamidreza Ebrahimisenu

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-05-10, 1398/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Scrophularia Striata Plant on Breast Fissure of Lactating women

Public title

The Effect of Scrophularia Striata on Breast Fissure of Lactating women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Single-child delivery A term and healthy infant and exclusive breast milk nutrition Birth weight of infant between 2500 to 4000 grams

Exclusion criteria:

Abnormality of mouth, palate, jaw or face in infant
Mother's disease to known underlying diseases (diabetes or any type of internal-surgical disease) History of nipple abnormalities (flat or inverted nipples or any nipple malformation which is followed by burning or any history of nipple and areola operation in childhood) History of identified mental illnesses in mother

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Using the number cruncher statistical system (NCSS) software, the samples will randomly assign to one of the two groups of Scrophularia striata and lanolin.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients became blind because of the appearance and color of the ointment. Due to lack of knowledge about the random allocation of patients to their intervention 1 and 2 group, the researcher was blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Asian Roads, Gonabad, Khorasan Razavi, Iran

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Postal code

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Approval date

2019-07-27, 1398/05/05

Ethics committee reference number

IR.GMU.REC.1398.076

Health conditions studied

1

Description of health condition studied

Breast Fissure

ICD-10 code

N64.0

ICD-10 code description

Fissure and Fistula of Nipple

Primary outcomes

1

Description

Reduction of nipple pain

Timepoint

Before intervention, day 3 and day 8 after intervention

Method of measurement

Using Numerical Rating Scale for measuring pain intensity

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

intervention group1: In the intervention group1 after breastfeeding 1gr Scrophularia striata cream will be rubbed to the nipple and areola 3 times a day for 7 days

Category

Treatment - Drugs

2

Description

intervention group2: in the intervention group two after breastfeeding 1gr Lanolin cream will be rubbed to the nipple and areola 3 times a day for 7 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ommolbanin Hospital

Full name of responsible person

Mohaddese Abbaspour

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2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr Shahla Khosravan

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Amirreza Nasirzadeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

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Other areas of specialty/work

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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