

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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)

###### Phone

+98 51 5722 3028

###### Email address

ebrahimi.h.stu@gmu.ac.ir

##### 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

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691987888

**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

**Street address**

Ayatolah Bahjat Street, Mashhad, Khorasan, Iran

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### 2

#### Recruitment center

**Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Mohaddese Abbaspour

**Street address**

the margin of Imam Reza Square, Ibn Sina Street,  
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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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Gonabad University of Medical Sciences, Asian Roads,  
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mma\_khosravan@yahoo.com

**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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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

### Contact

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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