

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the efficacy of erythromycin gel and protective breast and breast milk on breastfeeding lactating women

#### Protocol summary

##### Study aim

Comparison of the efficacy of breast milk and erythromycin gel and breast protector during breast fissure remission

##### Design

The randomized controlled clinical trial was performed with parallel groups, with no blinding

##### Settings and conduct

Breastfeeding mothers were required to explain the purpose of the study after being satisfied with the inclusion criteria and a written consent was obtained. Sampling is done in a lactation clinic of Mobini Hospital in Sabzevar, Iran, as a randomized interventional study.

##### Participants/Inclusion and exclusion criteria

Breastfeeding mothers who score at least three on the Estor scale and have a fever within the first six weeks after delivery, Infant with abnormalities in mouth and palate, maxillofacial and maternal skin diseases, autoimmune diseases and diabetes.

##### Intervention groups

The first group should apply erythromycin gel on the nipple and the aura three times daily as a finger band, The second group is to put the breast protector on the nipple before breastfeeding and hold it during sucking.

##### Main outcome variables

Breast severity; severity of pain caused by breast fissure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181214041970N1**

Registration date: **2019-12-01, 1398/09/10**

Registration timing: **prospective**

Last update: **2019-12-01, 1398/09/10**

Update count: **0**

##### Registration date

2019-12-01, 1398/09/10

##### Registrant information

###### Name

Fateme Shojaee

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3509 9349

###### Email address

fateme.sh7752@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-07-22, 1399/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the efficacy of erythromycin gel and protective breast and breast milk on breastfeeding lactating women

##### Public title

Comparison of the efficacy of erythromycin gel and protective breast and breast milk on breastfeeding lactating women

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Catch the fissure and get at least a score of three from the Storey scale Occurrence of fissure within the first 6 weeks after delivery Ages 18-35 years Exclusive Breastfeeding Normal-weight single-term labor(2500-4000) Willingness to participate in the study

### Exclusion criteria:

Infant with abnormalities in the mouth, palate, jaw and face The mother has nipple malformations or previous nipple surgeries Maternal skin disease and autoimmune diseases and diabetes Nipple sores

### Age

From **18 years** old to **35 years** old

### Gender

Female

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **135**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Sampling will be done as a randomized interventional study. In order to uniformize the degree of breast fissure, a stratified random method will be divided into two layers based on the degree of fissure. Each of the random allocation classes will be performed with hex blocks using a random number table.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Sabzevar University of Medical Sciences Ethics Committee

##### Street address

No. 55, First Floor, Dentist 19, Mashhad, Dental Boulevard,

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

09189855793

### Approval date

2019-11-16, 1398/08/25

### Ethics committee reference number

IR.MEDSAB.REC.1398.068

## Health conditions studied

### 1

#### Description of health condition studied

Breast fissure

#### ICD-10 code

O92.1

#### ICD-10 code description

Cracked nipple associated with pregnancy, the puerperium, and lactation

## Primary outcomes

### 1

#### Description

Severity of breast fissure

#### Timepoint

Before intervention,Third day after intervention,Seventh day after intervention

#### Method of measurement

Standard Store Scale

## Secondary outcomes

### 1

#### Description

Severity of breast pain

#### Timepoint

Before intervention,Third day after intervention,Seventh day after intervention

#### Method of measurement

Standard Visual Pain Scale

## Intervention groups

### 1

#### Description

Intervention group 1: Mothers were asked to apply erythromycin gel as much as one finger three times daily on the nipple and the surrounding aura,Intervention group 2: Place the breast protector on the nipple before breastfeeding and hold it while sucking.

#### Category

Treatment - Other

### 2

#### Description

Control group: The mothers were instructed to pour three or four drops of breast milk on each nipple and aura after each lactation and allow it to dry.

#### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Health Center Breastfeeding Clinic

**Full name of responsible person**

Mojdeh Navinejad

**Street address**

first floor, No. 13, Shirin dead end, 45 Ibn Yamin Street, Sabzevar

**City**

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**Province**

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**Postal code**

9613883778

**Phone**

+98 21 4423 5198

**Email**

mojdemw@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Fereshte Ghorat

**Street address**

Above the Memorial of Unknown Martyrs Campus of Sabzevar University of Medical Sciences, Boulevard Shohadaye hastei, Sabzevar

**City**

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**Province**

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9617913114

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**Email**

drghorat@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Sabzevar 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**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Mojdeh Navinejad

**Position**

Master of Midwifery

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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first floor, No. 13, Shirin dead end, 45 Ibn Yamin Street, Sabzevar

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

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**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**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Fateme Shojaee

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Midwifery

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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**

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