

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison efficacy of Olive Oil and Aloe vera extract on healing of breast fissure in breastfeeding women

#### Protocol summary

##### Summary

The objective of this randomized clinical trial is comparing efficacy of olive oil and aloe vera extract on healing of breast fissure in breastfeeding women. The sample size will be determined on the basis of a pilot study. Samples randomly (by permutation blocks) will be divided into intervention and control groups. The inclusion criteria include: having breast fissure and a minimum score of 3 of Store scale; Incidence of breast fissures in first 6 weeks after childbirth; exclusive breastfeeding mothers; Term Single birth pregnancies with normal weight; lack of abnormalities in the mouth, palate, jaw and face of newborn; the absence of infection or previous surgery of nipple; lack of abnormalities of nipple and areola ; not suffering from mental disorders. Exclusion criteria included the bottle-fed infants; use of milking breast or breast shield; oral fungal infection of the newborn; abscess or fungal infection of the breast; The first group of mothers use olive oil and the second group use aloe vera extract three times a day on the nipple and areola of the breast. The third group after each breastfeeding rubbing their milk on the nipple and areola 4-3 drop and allow to dry. the first and second group mothers In addition to the considered intervention rub their milk on the nipple and areola. The main variable are olive oil, aloe vera extract and breast milk that their effect on healing of breast fissure will be measured and compared

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015010320544N1**

Registration date: **2015-02-08, 1393/11/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-02-08, 1393/11/19

##### Registrant information

###### Name

Mina Mesbah

###### Name of organization / entity

Gonabad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 5722 3028

###### Email address

mesbah.mina@gmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Gonabad University of Medical Sciences

##### Expected recruitment start date

2015-01-20, 1393/10/30

##### Expected recruitment end date

2015-04-19, 1394/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison efficacy of Olive Oil and Aloe vera extract on healing of breast fissure in breastfeeding women

##### Public title

Comparison efficacy of Olive Oil and Aloe vera extract on healing of breast fissure

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

The inclusion criteria include: The incidence of breast fissure and a minimum score of 3 on store scale: incidence fissures in the first 6 weeks after childbirth: age between 18 and 40 years: have a telephone for follow-up: exclusive breastfeeding mothers; Term Single birth pregnancies with normal weight; lack of abnormalities in the mouth, palate, jaw and face of newborn: lack previous surgery or abnormalities of nipple and areola: not suffering from mental disorders. Exclusion criteria include: the bottle-fed infants: use of milking breast or breast shield : oral fungal infection of the newborn :abscess or fungal infection of the breast: Baby feeding bottle: use of interface milking breast: oral fungal infection of the newborn: abscess or fungal infection of the breast: The use of other therapies other than the recommended treatment: Unwillingness to continue cooperation in the study: non-compliance interval intervention

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size:

**Randomization (investigator's opinion)**

Randomized

**Randomization description****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**

Ethics Committee of Gonabad University of Medical Sciences

**Street address**

Gonabad UGonabad University of Medical Sciences, Next to the Asian Road

**City**

Gonabad

**Postal code****Approval date**

2015-01-07, 1393/10/17

**Ethics committee reference number****Health conditions studied****1****Description of health condition studied**

breast fissure

**ICD-10 code**

O92.1

**ICD-10 code description**

Cracked nipple associated with childbirth

**Primary outcomes****1****Description**

The severity of breast fissure

**Timepoint**

Days of first, third and seventh

**Method of measurement**

store scale

**Secondary outcomes****1****Description**

intensity of pain caused by breast fissure

**Timepoint**

days of first, third and seventh

**Method of measurement**

Visual Analoge Scale

**2****Description**

The extent of damage caused by breast fissure

**Timepoint**

days of first, third and seventh

**Method of measurement**

Amir criteria

**Intervention groups****1****Description**

The first group of mothers rub about 3-4 drops of their milk on the nipples and around areola after each feeding and allow it to dry, in addition use 5.0 ml of olive oil on the nipple and areola three times a day.

**Category**

Treatment - Other

**2****Description**

The second group of mothers rub 3-4 drops of their milk on the nipples and around areola after each feeding and

allow to dry, in addition use 0/5ml of aloe vera extract three times a day on the nipple and areola.

**Category**

Treatment - Other

**3****Description**

The third group(control group) rub 4-3 drops of their milk on the nipple and areola after each feeding and allow it to dry

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Gonabad University of Medical Sciences, 22 Bahman Hospital

**Full name of responsible person**

Mina Mesbah

**Street address**

Gonabad University of Medical Sciences, Next to the Asian Road

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Gonabad University of Medical Sciences

**Full name of responsible person**

Doctor Ali Mohammadpour

**Street address**

Gonabad University of Medical Sciences, Next to the Asian Road

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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, Gonabad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Mina Mesbah

**Position**

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Maryam Eshghizadeh

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**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*