

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

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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

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Position

MSC Student in Nursing Education

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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