Clinical Trial Protocol
Iranian Registry of Clinical Trials
13 Jan 2022

The effect of Cucurbita Pepo seed oil on the severity of nipple fissure and nipple pain in lactating women

Protocol summary

Study aim
The effect of pumpkin seed oil on severity of fissure and nipple pain in lactating women

Design
A randomized controlled clinical trial with parallel, randomized groups

Settings and conduct
This study is conducted in community health centers of Gonabad city. Breastfeeding lactating women in the intervention group used pumpkin seed oil in a way that the researcher explained to them. Before and after the intervention, the pain intensity and fissure of the breast will be measured using storey scales and visual analogue of pain. Finally, the results are analyzed with the help of statistical software.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of nipple fissure Obtain a minimum score of 3 from the Storr scale Incidence of fissure in the first 6 weeks after delivery Age between 18 and 40 years Exclusive Breastfeeding Term Single Birth with Newborn Normal Weight (4000-2500 g) Infant does not have malformations in the mouth, palate, jaw and face in the mouth Lack of maternal nipple abnormalities, including nipple or previous history of breast and areol surgeries Mother does not use of shower milk or breast interface Infant does not have oral fungus Exclusion criteria: Start feeding the baby with a glass of milk after entering the study Use a breast milk or breast interface after inclusion Infant with oral fungus after inclusion Maternal AIDS or Breast Fungal Infection After Inclusion Maternal use of treatments other than the recommended treatment unwillingness to continue collaborating on the study Losing one of the follow up turns

Intervention groups
Intervention group includes patients with nipple pain and fissure who receive an intervention in the form of egg oil. The control group consisted of patients with pain and fissure of the breast who received routine intervention.

Main outcome variables
Severity of fissure and nipple pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: IRCT20200216046512N1
Registration date: 2020-03-18, 1398/12/28
Registration timing: prospective

Last update: 2020-03-18, 1398/12/28
Update count: 0

Registration date
2020-03-18, 1398/12/28

Registrant information
Name
Mehri Saffari
Name of organization / entity
Country
Iran (Islamic Republic of)

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+98 51 5722 1108

Email address
saffari.m@gmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-03, 1399/01/15

Expected recruitment end date
2020-07-05, 1399/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
Scientific title
The effect of Cucurbita Pepo seed oil on the severity of nipple fissure and nipple pain in lactating women

Public title
“The effect of Cucurbita Pepo seed oil on the severity of nipple fissure and nipple pain”

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
- Diagnosis of nipple fissure
- Obtain a minimum score of 3 from the Storr scale
- Incidence of fissure in the first 6 weeks after delivery
- Age between 18 and 40 years
- Exclusive Breastfeeding Term
- Single Birth with Newborn
- Normal Weight (4000-2500 g)
- Infant does not have malformations in the mouth, palate, jaw and face
- Lack of maternal nipple abnormalities, including nipple or previous history of breast and areol surgeries
- Lack of maternal skin diseases and allergies based on maternal self-report
- Lack of maternal mental illness based on maternal self-report
- Infant does not have oral fungus
- A history of hypersensitivity to pumpkin seed oil or other components of the pumpkin plant based on maternal self-report
- Having a desire to participate in the study
- Having an active hotline for study pursuits

Exclusion criteria:
- Start feeding the baby with a glass of milk after entering the study
- Use a breast milk or breast interface after inclusion
- Infant with oral fungus after inclusion
- Maternal AIDS or Breast Fungal Infection After Inclusion
- Maternal use of treatments other than the recommended treatment
- Unwillingness to continue collaborating on the study
- Losing one of the follow up turns
- Failure to observe interval

Age
From 18 years old to 40 years old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
First, out of the community health centers in the city, three centers were selected by simple random sampling and then according to the volume of referrals to the centers, the research units were selected from among the eligible individuals. Individuals will be assigned to intervention and control groups using a randomized block-by-block method with random number table.

Blinding (investigator's opinion)
Not blinded

Primary outcomes

1

Description of health condition studied
Nipple fissure

ICD-10 code
N64.0

ICD-10 code description
Fissure and fistula of nipple

Secondary outcomes
empty

Intervention groups
Not used
Description
Intervention group: Eight hours before use, test the oil on the arm skin and apply it to the nipple area if no itching or redness occurs. How to use pumpkin seed oil is that mothers should apply 0.5 to one milliliter (five to ten drops) of oil three times a day for seven days on the nipple and the surrounding area. Pumpkin seed oil should remain in place for at least one hour.

Category
Treatment - Other

Description
Control group: Mothers should apply five to ten drops of breast milk three times a day for seven days on the nipple and the aura around it, allowing it to dry for at least an hour.

Category
Treatment - Other

Recruitment centers

Recruitment center
Name of recruitment center
County community health centers
Full name of responsible person
Mehri Saffari
Street address
No 28, 7th Alley, Naserkhosro Street
City
Gonabad
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9691837173
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Sponsors / Funding sources

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Shahla Khosravan
Street address
Asian Road Margin - Gonabad University of Medical Sciences
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Person responsible for general inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Saffari mehri
Position
Midwifery student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
No.28, 7th Alley, Naserkhosro street
City
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Email
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Saffari
Position
Midwifery student
Latest degree
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Other areas of specialty/work
Midwifery

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saffari.m@gmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Saffari

Position
Midwifery student

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
No.28, 7th Alley, Naserhosro street

City
Gonabad

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