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
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Name of organization / entity
Country
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Email address
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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 in the mouth
- 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
- Mother does not use 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 of 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

**Health conditions studied**

**ICD-10 code**
N64.0

**ICD-10 code description**
Fissure and fistula of nipple

**Primary outcomes**

**Description of health condition studied**
Nipple fissure

**Timepoint**
Measurement of severity of nipple fissure at baseline (before intervention) and 3, 8 days after pumpkin seed oil intake

**Method of measurement**
Visual Analogue Scale

**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: Mehr Saffari
Street address: No 28, 7th Alley,Naserkhosro Street
City: Gonabad
Province: Razavi Khorasan
Postal code: 9691837173
Phone: +98 51 5722 1108
Email: saffari.m@gmu.ac.ir

**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
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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: Bachelor
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<td><a href="mailto:saffari.m@gmu.ac.ir">saffari.m@gmu.ac.ir</a></td>
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**Person responsible for updating data**

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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