Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Boswellia and Lanolin ointment on fissure improvment and pain intensity of the nipple

Protocol summary

Study aim
Comparison of the effectof Boswellia and Lanolin ointment on fissure improvment and pain intensity of the nipple

Design
A triple- blind clinical trial with parallel groups on 60 eligible breastfeeding women will be performed and the random allocation of the groups will be done by randomization sequencing by the SPSS software.

Settings and conduct
In Mashhad health selected centers (2,5), the right way of breastfeeding and using medicine (2 times per day, immediately after breastfeeding for seven days (a week), will be taught to two group, and before the second breastfeeding.The breast should be washed with warm water.The Stoure score before the intervention of third day and eighth day will be registered by researcher.

Participants/Inclusion and exclusion criteria
Inclusion criteria: all lactating women with term and healthy infants who suffering from cracked and nipple pain. Exclusion criteria: mothers whose infant uses a pacifier or feeding bottle, mothers who have any allergies to Boswellia and Lanolin

Intervention groups
Intervention group: routine care and education on the correct way of breastfeeding, topical application of Boswellia ointment twice a day after breastfeeding for up to seven days, washing breast with warm water before breastfeeding. Control group: routine care and education on the correct way of breastfeeding, topical application of Lanolin ointment twice a day after breastfeeding for up to seven days, Washing breast with warm water before breastfeeding

Main outcome variables
Fissure and nipple pain score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181203041833N1**
Registration date: **2019-02-22, 1397/12/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-22, 1397/12/03**
Update count: **0**

Registration date
2019-02-22, 1397/12/03

Registrant information

Name
Masoumeh Mobaraki

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-10, 1397/11/21

Expected recruitment end date
2019-10-22, 1398/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Boswellia and Lanolin ointment on fissure improvment and pain intensity of the nipple

Public title
Comparison of the effect of Boswellia and Lanolin on fissure and pain of the nipple
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Mothers who suffering from nipple pain and nipple fissure Iranian Literate Singleton birth Term and healthy infant and exclusively breast fed Infant weight 2500 to 4000 grams Infant without any mouth or palate or jaw or face anomaly Mother without any identified mental disease Mother without any nipple malformation (flat or inverted nipples or any nipple malformation which is followed by burning or any history of nipple and areola operation in childhood) Mothers don't suffer from known background diseases such as diabetes or any kind of internal_surgical diseases
Exclusion criteria:
The infant uses a pacifier or feeding bottle Mothers who do have any allergy to Boswellia and Lanolin
Age
No age limit
Gender
Female

Phase
Bioequivalence
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomized allocation is based on health centers, so that from among the 4 selected health centers on the basis of the lottery, two centers will be allocated to the Lanolin group and two centers will be allocated to the group of Boswellia. Then the clients of each center receive the appropriate treatment. The random allocation of centers to individuals is to prevent the publication of information.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The Iranian-made lanolin ointment is prepared in a colorless manner, similar to the mixture of chopped pomace, and then both drugs are placed in the same cans and sizes as the pharmacy mark (a,b) so that the researcher and the unit research does not know its content
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Ethics Committee for Biomedical Research of Mashhad Univercity of Medical Sciences
Street address
Ibn Sina Street, School of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2018-12-03, 1397/09/12
Ethics committee reference number
IR.MUMS.NURSE.REC.1397.068

Health conditions studied

1

Description of health condition studied
Fissure of nipple
ICD-10 code
O92.1
ICD-10 code description
Cracked nipple associated with childbirthFissure of nipple, gestational or puerperal

Primary outcomes

1

Description
Score of fissuer and nipple pain
Timepoint
Day 3 and 8 after intervention
Method of measurement
The stour scale for fracture and the visual scale of pain for the severity of pain

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group: correct breastfeeding and Boswellia ointment administration amount 1gr are taught (twice a day immediately after breastfeeding for seven days) and rinsed with warm water before

breastfeeding.The stour scale will be recorded by the researcher at the stages before the intervention, the third and eighth day after the intervention

Category

Treatment - Drugs

2

Description

Control group: correct breastfeeding and Lanolin ointment administration amount 1gr are taught (twice a day immediately after breastfeeding for seven days) and rinsed with warm water before breastfeeding.The stour scale will be recorded by the researcher at the stages before the intervention, the third and eighth day after the intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Health Center No.5 of Mashhad

Full name of responsible person
Dr BratAli Arab Nejad

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2

Recruitment center

Name of recruitment center
Health Center No. 2 of Mashhad

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Masoumeh Mobaraki

Position
Midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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