Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of Commiphora mukul cream on improvement of breast engorgement of women referred to the health center of Kerman University of medical science in 2015-2016

Protocol summary

Summary

Objectives: The aim of this study is to assess the effect of Commiphora mukul cream improvement of breast engorgement. Study Design: This study is randomized, triple blinded and with placebo control. 100 lactating Women will be allocated into two groups. They will receive Commiphora mukul or placebo cream. At the begining two groups will receive correct feeding technique. In the drug group mothers apply an amount of Commiphora mukul cream on breast after feeding 10 times a day for 2 days. However, the controlled groups will consume placebo cream instead of Commiphora mukul cream. Inclusion criteria include: The incidence of breast engorgement; Term Single birth pregnancies with normal weight; The lack of abscess, fissure and mastitis; General temperature lower than 38 ° C and Lack of allergy to Commiphora mukul. Exclusion criteria include: The incidence of allergy to Commiphora mukul and Increased general temperatures more than 38 ° C. Main outcome variables: The Checklist breast engorgement is completed using the total score is obtained for the symptoms of engorgement (Severity Index= Erythema+ Breast Tension+ Breast Pain) before the study, on day 2 after the study by the investigator to evaluate breast engorgement intensity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062633812N2**
Registration date: **2017-07-19, 1396/04/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-19, 1396/04/28

Registrant information

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Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Sponsor 1 research and technology department of Shahid Beheshti University of Medical Sciences, Teh

Expected recruitment start date
2016-09-22, 1395/07/01

Expected recruitment end date
2017-06-10, 1396/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of Commiphora mukul cream on improvement of breast engorgement of women referred to the health center of Kerman University of medical science in 2015-2016

Public title

The effect of Commiphora mukul cream improvement of breast engorgement

Purpose
Treatment
Inclusion/Exclusion criteria
The study inclusion criteria for the Iranian; literate mothers who were in the 1st to 15th days after delivery consisted of having breast engorgement with a minimum intensity score of 2 based on the checklist (with a maximum score of 19); A sublingual temperature below 38 ° C; Having had engorgement symptoms during the first 15 days after delivery; No use of medications for stopping breastfeeding; No use of topical herbal therapies; Not having developed breast abscess or mastitis; No prohibition on lactation; No history of any allergies to Commiphora mukul or other plants; And nursing every 2 to 3 hours. For the neonates, the inclusion criteria consisted of being a singleton and having a full-term birth and normal birth weight (2500-4000 g); Being able to suck on nipples; Not being prohibited from breastfeeding; And demanding to be nursed every 2 to 3 hours. The study exclusion criteria for the mothers consisted of the incidence of allergy to Commiphoramukul; A general temperature exceeding 38 ° C after beginning the intervention; Use or need to antiinflammatory medications or painkillers or warm compress or cold compress or acupressure interfering with the designed intervention during the course of the study; And the incidence of unexpected events for either participants interfering with their breastfeeding; Use of the proposed treatment less than five times a day. The infants were excluded from the study if they lost the study inclusion criteria for any reason, including getting a fever during the course of the intervention.
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional Ethics Committee of the Faculty of Pharmacy and Nursing Midwifery of Shahid Beheshti U
Street address
Vali-Asr Avenue, Cross of Vali-Asr and Niayesh Highway, opposite to Rajaee Heart Hospital, Tehran, Iran
City
Tehran
Postal code
1985717443
Approval date
2016-06-09, 1395/03/20
Ethics committee reference number
IR.SBMU.PHNM.1299.312

Health conditions studied

1

Description of health condition studied
Breast engorgement
ICD-10 code
P83.4
ICD-10 code description
Breast engorgement of newborn

Primary outcomes

1

Description
Erythema breast
Timepoint
Before intervention,2 days after intervention
Method of measurement
Check list of breast engorgement

2

Description
Breast Tension
Timepoint
Before intervention,2 days after intervention
Method of measurement
Check list of breast engorgement

3

Description
Breast pain
Timepoint
Before intervention,2 days after intervention
Method of measurement
Check list of breast engorgement

4

Description
Total score breast engorgement

Timepoint
Before intervention,2 days after intervention
Method of measurement
Check list of breast engorgement

Secondary outcomes

1

Description
Side effects of commiphora mukul cream
Timepoint
Before intervention,2 days after intervention
Method of measurement
Q&A; Visual analog

Intervention groups

1

Description
0.5 ml Placebo cream will be rubbed to breast from the top to the nipple; 10 times a day; for 2 days
Category
Placebo

2

Description
0.5 ml Commiphora mukul cream will be rubbed to breast from the top to the nipple; 10 times a day; for 2 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital of Kerman
Full name of responsible person
Dr. Aliasghar Vahidi
Street address
Imam Khomeini Highway, Kerman, Iran
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
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Vali-Asr Avenue, Cross of Vali-Asr and Niayesh Highway, opposite to Rajaee Heart Hospital, Tehran, Iran
City
Tehran
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 Shahid Beheshti 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
Shahid Beheshti University of Sciences,Tehran
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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