

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

2017-07-19, 1396/04/28

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 beginning 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

Registrant information

Name

Shahrzad Zolala

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

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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

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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 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

Full name of responsible person

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Position

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Highway, Tehran, Iran**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*