

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of Ginger compress on breast engorgement in Lactating Women

Protocol summary

Study aim

To determine the effect of Ginger compress on breast engorgement in Lactating Women

Design

Randomized Clinical Trial study was conducted on 76 eligible lactating women who were admitted to the study that people accidentally block that blocks normal delivery or cesarean, In this study fall into two groups

Settings and conduct

The intervention is performed three times a day for two days on the breast (right or left or both) done. Breast engorgement is recorded before and 12 to 24 hours after the end of the interventions according to the checklist for breast engorgement score. Blind was not possible due to the scent of ginger.

Participants/Inclusion and exclusion criteria

Inclusion and Exclusion criteria: Iranian and resident of Mashhad , Having a desire to participate in the study, Have at least reading and writing skills; Has a baby for 2 to 5 days after delivery ,a minimum score of 2 out of 19 breast congestion score based on the severity of the Czech list; Pain score based on the visual scale of pain more than 2 ,lack of mastitis, lack of high-risk pregnancy and childbirth, Sensitivity to ginger during use, Accident and stressful events during the study, the occurrence of certain problems for the neonate

Intervention groups

Interventions in breast congestion control group consisted of routine actions (including proper breastfeeding techniques and hot compress..) Interventions in the intervention group: the routine for breast engorgement, ginger compress for 30 minutes Three times a day for two days on the breast (right or left or both) done. before and after the intervention Breast engorgement is recorded according to the checklist for breast engorgement score. the first treatment is by Researcher

Main outcome variables

The severity of breast engorgement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180508039585N1**

Registration date: **2018-05-15, 1397/02/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-15, 1397/02/25**

Update count: **0**

Registration date

2018-05-15, 1397/02/25

Registrant information

Name

maryam monazami vazifehdost

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3881 0193

Email address

monazzamivm951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-13, 1397/02/23

Expected recruitment end date

2018-08-14, 1397/05/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ginger compress on breast engorgement in Lactating Women

Public title

The effect of Ginger compress on breast engorgement in Lactating Women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian and resident of Mashhad Having a desire to participate in the study Have at least reading and writing skills Having a phone to access the person Gestational age at delivery is complete between 37 to 42 weeks Healthy full-term singleton birth (4000-2500 g) It is breastfeeding and intends to continue lactation Exclusive breastfeeding pattern The risk of breast engorgement in 2 to 5 days after delivery Not having a history of or current illness lack of high-risk pregnancy and childbirth No history of breast surgery Mother temperature lower than 38 ° C A minimum score of 2 out of 19 breast congestion score based on the severity of the Czech list Pain score based on the visual scale of pain more than 2 Do not use medication that suppresses lactation Non-use of topical herbal remedies in the breast lack of mastitis (according to the gynecologist) Having certain problems for the neonate that leads to impairment in breastfeeding

Exclusion criteria:

Increase temperatures at the mother to more than 38 ° C after intervention Breastfeeding intervals greater than 3 hours Not wanting to continue collaborating in the study Take less than 5 treatment interventions The treatment interval is less than 6 hours and more than 8 hours During the course of treatment to mastitis or breast abscesses Lack of access to the participant 12 to 24 hours after the intervention Sensitivity to ginger during use Accident and stressful events during the study The occurrence of certain problems for the neonate that lead to impairment in breastfeeding.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized Clinical Trial clinical trial people accidentally block that blocks normal delivery or cesarean, In this study fall into two groups. This method will be done using the PASS (Power Analysis and Sample Size) software

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

کمیته اخلاق دانشگاه علوم پزشکی مشهد

Street address

Qureishi building, Daneshgah Ave, Mashhad, Razavi Khorasan

City

Mashhad

Province

Razavi Khorasan

Postal code

۹۱۷۳۵-۹۵۱

Approval date

2018-04-07, 1397/01/18

Ethics committee reference number

IR.MUMS.REC.1397.008

Health conditions studied**1****Description of health condition studied**

Breast engorgement

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The severity of breast engorgement

Timepoint

Before and 12 to 24 hours after the end of the interventions

Method of measurement

Breast congestion list

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Interventions in breast congestion control group consisted of routine actions (including proper breastfeeding techniques and hot compress..)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emamreza hospital

Full name of responsible person

Dr.abdollah bahrami

Street address

Enesina Ave, Daneshgah Ave, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

Bahramia@mums.ac.ir

2

Recruitment center

Name of recruitment center

Quaem hospital

Full name of responsible person

Dr.Ali Mehri

Street address

Ahmad Abad Ave, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

91199-91766

Email

MehriA1@mums.ac.ir

3

Recruitment center

Name of recruitment center

Omolbanin hospital

Full name of responsible person

Dr Fateme Tara

Street address

16, Bahgat Ave, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Email

taraf@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen Tafaghodi

Street address

Qureishi bulding, Daneshgah Ave, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

91735-951

Email

tafaghodim@mums.ac.ir

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

Maryam Monazami vazifeh dost

Position

Master of science student of midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No. 4, Honarestan 16 Ave, Vakil abad Blvd , Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

91786-58411

Phone

+98 51 3881 0193

Email

monazzamivm951@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Sedigheh Yousefzadeh

Position

Associate professor

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Ebne Sina Street, Daneshgah Ave, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

yousefzades@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Monazami vazifehdost

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Bahar Ave., Medical Army Hospital., Mashhad Town

City

Mashhad

Province

Razavi Khorasan

Postal code

91786-58411

Phone

+98 51 3881 0193

Fax

Email

monazzamivm951@mums.ac.ir

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable