

# 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**

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**Province**

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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

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91199-91766

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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

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13944-91388

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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

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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

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

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Sedigheh Yousefzadeh

**Position**

Associate professor

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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## 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

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Bahar Ave., Medical Army Hospital., Mashhad Town

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**Phone**

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**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