

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Clinical trial Study of the Effect of Ginger Plant Capsules on Reducing the Pain in Women with Postpartum Pain

Protocol summary

Summary

This study was designed to investigate the effect of Zingiber capsule (Zintoma) on reducing postpartum after pain. 124 women who will be admitted in Mahdieh hospital postpartum unit participate according to inclusion criteria including vaginal delivery at the gestational age more than 38 weeks or birth weight more than 2500 grams; at least one breast feeding session after delivery; absence of allergy to any herbal medicine; absence of addiction to narcotic drugs; absence of excessive hemorrhage, diabetes, hypertension and persistent fever. Ginger and placebo 250 mg capsules, prepared by Gol-Daru company, will be kept in a box next to each other for one week to get same smell. This job will be done by a trusted midwife without researcher's knowledge. Then the midwife will put 4 capsules in each box and will label A or B. If they are satisfied to participate in the study, they have to complete demographic questionnaire. 2 hours after delivery, the severity of pain will be measured by Higam chart and if they acquire score 4 or more, the researcher will give them 2 A or B capsules with 2 Mefenamic acid capsules (as a routine treatment). Then pain intensity will be charted half an hour, one hour and two hours after taking medication. The second and third dose (one capsule) is administered every 8 hours. If they need extra sedative, they should record the time and the number of extra medications. Main outcomes: pain intensity and pain relief time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707283860N33**

Registration date: **2017-11-17, 1396/08/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-17, 1396/08/26

Registrant information

Name

Gity Ozgoli

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

gozgoli@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of International Branch of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-08-06, 1396/05/15

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial Study of the Effect of Ginger Plant Capsules on Reducing the Pain in Women with Postpartum Pain

Public title

Clinical trial Study of the Effect of Ginger Plant Capsules on Reducing the Pain in Women with Postpartum Pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Iranian with reading and writing skills; Delivery by vaginal method; Pregnancy age of 38 weeks and more; The baby's weight more than 2500 grams; Having a living and normal baby; Mothers without previous cesarean or surgery history; lasting 2 hours after delivery; childbirth without the help of instrument (Vacuum and Forceps) or pressure on the uterus; absence of drug addiction; having no history of allergies to ginger and herbal medicine; mother with complains of after pain; absence of uses of medications and analgesia (epidural anesthesia, Spinal anesthesia, Entonox and pethidine) during labour; the mother is not affected by chronic disease, such as diabetes and hypertension; spontaneous existence of placenta and membrane. Exclusion Criteria: Maternal complications such as increased postpartum hemorrhage, fever and blood pressure over 140/90; requiring surgery and anesthetics.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

This study was a three-blind study in which the researcher, samples and counselor are not known about the type of capsules. The capsules are placed in a coded container and randomly given to the participants.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Pharmacy and Midwifery Medical schools, Shahid Beheshti University of Medical Sci

Street address

Niyayesh Highway, Valiasr st

City

Tehran

Postal code

Approval date

2017-07-01, 1396/04/10

Ethics committee reference number

IR.SBMU.PHNM.1396.782

Health conditions studied

1

Description of health condition studied

Postpartum pain

ICD-10 code

Z39

ICD-10 code description

Postpartum care and examination

Primary outcomes

1

Description

Pain intensity

Timepoint

Before the intervention, half, one and two hours after intervention, then every 8 hours

Method of measurement

Numerical Measurement Scale

Secondary outcomes

1

Description

The number of additional painkiller intake

Timepoint

2 hours after delivery and then every 8 hours for 24 hours

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Mefenamic acid at the dose of 500 mg (two 250mg capsules) plus Zintoma, Produced by Gol Dara Company, at the dose of 500 mg (two 250mg capsules) are prescribed two hours after delivery and then one Mefenamic acid and Zintoma are prescribed every 8 hours until 24 hours.

Category

Treatment - Drugs

2

Description

Control group: Mefenamic acid at the dose of 500 mg (two 250mg capsules) plus placebo (containing Chickpea Flour Produced by Gol Daru similar to Zintoma in Dose and shape), at the dose of 500 mg (two 250mg

capsules) are prescribed two hours after delivery and then one Mefenamic acid and one placebo are prescribed every 8 hours until 24 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational and Medical Center of Mahdieh

Full name of responsible person

Shabnam Mozafari

Street address

Rajabnia avenue, Shishegar avenue, Fadayean eslam street, Shosh Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of International Branch of Shahid Beheshti University of Medical Scien

Full name of responsible person

Rahimi Abbas

Street address

N19., near Hemat bridge, Tavanir ave., Valiasr st

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 of International Branch of Shahid Beheshti University of Medical Scien

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 Medical Sciences

Full name of responsible person

Giti Ozgoli

Position

PhD of reproductive health

Other areas of specialty/work

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Person responsible for scientific inquiries

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Giti Ozgoli

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shabnam Mozafari

Position

Master student of midwifery

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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