

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison of ginger suppository and placebo on headache and chills after spinal anesthesia in cesarean section patients

#### Protocol summary

##### Study aim

The effect of ginger suppository on the treatment of headache and chills after spinal anesthesia in cesarean section patients

##### Design

This study has two groups (intervention group and control group) and is a single blind randomized clinical trial. Randomization is a probabilistic method with quadruple balanced blocks that is performed by a software. The sample size was calculated based on G<sub>POWER</sub> software (50 people in each group). The clinical trial phase is 3.

##### Settings and conduct

This study will be performed in the Women's Referral Hospital (Kamali Hospital) in Karaj. This study is a parallel and single blind randomized clinical trial. Patients do not know which drug is the main drug and which is the placebo. In the intervention group main drug (ginger suppository) will be used. In the control group, a placebo is used, which is like the main drug in all aspects such as smell, color and weight. In each group, pain intensity will be measured at 6 time points (0.5, 1, 1.5, 3, 6, 12 hours) after the operation. The severity of chills is recorded from 20 to 95 minutes after cesarean section, every 15 minutes for one minute.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 15-49 years, full-term pregnancy (37 full weeks of pregnancy), singleton pregnancy, anesthesia class ASA I- ASA II, non-emergency cesarean section, headache in the first 72 hours. Non-inclusion criteria: prolonged cesarean section (more than one hour), ginger allergy, use of psychotropic drugs

##### Intervention groups

The main drug (ginger suppository) will be used in the intervention group. In the control group, a placebo is used, which is like the main drug in all aspects (smell, color, weight).

##### Main outcome variables

The severity of headache; the severity of chills

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180110038302N8**

Registration date: **2021-12-14, 1400/09/23**

Registration timing: **prospective**

Last update: **2021-12-14, 1400/09/23**

Update count: **0**

##### Registration date

2021-12-14, 1400/09/23

##### Registrant information

##### Name

Mansoureh Yazdkhasti

##### Name of organization / entity

Alborz University medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4401 8856

##### Email address

m.yazdkhasti@abzums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-09-22, 1401/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of ginger suppository and placebo on headache and chills after spinal anesthesia in cesarean section patients

## Public title

The effect of ginger suppository on the treatment of headache and chills after spinal anesthesia

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Women aged 15 to 49 years Full-term pregnancy (37 full weeks of pregnancy) Singleton pregnancy Anesthesia class ASA I, ASA II(American Society of Anesthesiologists Physical Status Classification ) Non-emergency cesarean section Headache in the first 72 hours

### Exclusion criteria:

The cesarean section lasted more than an hour Attempted more than twice for spinal anesthesia Sensitivity to ginger Taking psychotropic drugs or narcotics Alcoholism

## Age

From **15 years** old to **49 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

First, a list of eligible people is prepared in Excel software. Then, the subjects are divided into two groups of intervention and control by block randomization method with 4 equal blocks, which is done with websites( www.randomization.com can do block randomization more easily). In this method, the size of all blocks is equal. In this study, with a 100 sample size, the number of blocks is 4 and the size of each block is 25. Two blocks (50 people) belong to an intervention group and two blocks (50 people) belong to the control group.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

This study is single blind. The patient does not know which drug is the main drug and which is the placebo. The intervention group is given the main drug and the control group is given the placebo. The color, smell, weight, and other characteristics of the placebo are as the same as the main drug.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

##### Street address

NO.14, Medicine school, Ooge Blvd, West BooAli Highway

##### City

Karaj

##### Province

Alborz

##### Postal code

3149969415

#### Approval date

2020-02-17, 1398/11/28

#### Ethics committee reference number

IR.ABZUMS.REC.1399.123

## Health conditions studied

### 1

#### Description of health condition studied

Headache and chills after spinal anesthesia in women with cesarean section

#### ICD-10 code

O74.5

#### ICD-10 code description

Spinal and epidural anesthesia-induced headache during labor and delivery

## Primary outcomes

### 1

#### Description

Headache score in Visual scale of pain

#### Timepoint

In both groups, pain intensity will be measured at 6-time points (0.5, 1, 1.5, 3, 6, 12) hours after the operation

#### Method of measurement

visual scale of pain questionnaire

### 2

#### Description

Shivering score in Crossley and Mahajan questionnaire

#### Timepoint

The severity of chills, from 20 to 95 minutes after cesarean section every 15 minutes

#### Method of measurement

Crossley and Mahajan questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The main drug (ginger suppository) is given to the patient after cesarean section. A ginger suppository is given every 8 hours for the first 24 hours after cesarean section. The manufacturer of medicine is the Faculty of Pharmacy of Alborz University. This suppository is not available in the market.

#### Category

Treatment - Other

### 2

#### Description

Control group: "Placebo in the form of a ginger suppository" is given to the patient in the form of ginger suppository after cesarean section. A placebo is given as a ginger suppository every 8 hours for the first 24 hours after cesarean section. The manufacturer of medicine in the Faculty of Pharmacy of Alborz University. This suppository is not available in the market.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kamali hospital

##### Full name of responsible person

Banafsheh Mashak

##### Street address

Kamali St, Taleghani St, Kamali Hospital

##### City

Karaj

##### Province

Alborz

##### Postal code

3149969415

##### Phone

+98 26 3264 2817

##### Email

Mansoyazd@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Alborz University of Medical Sciences

##### Full name of responsible person

Hatam Godini

#### Street address

45 meters Golshahr - Saffarian Alley - Deputy of Research and Technology

#### City

Karaj

#### Province

Alborz

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#### Phone

+98 26 3264 2815

#### Email

Mansoyazd@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Alborz 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

Alborz University of Medical Sciences

##### Full name of responsible person

Mansoureh Yazdkhasti

##### Position

Faculty Member

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Midwifery

##### Street address

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## Person responsible for scientific

## inquiries

### Contact

**Name of organization / entity**

Alborz University of Medical Sciences

**Full name of responsible person**

Mansoureh Yazdkhasti

**Position**

Faculty Member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Alborz University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

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

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is potentially shareable after unidentified individuals.

**When the data will become available and for how long**

"Access period starts 6 months after the results are published".

**To whom data/document is available**

Our data will be available to researchers working in academic and scientific institutions, or to people who are also involved in the industry.

**Under which criteria data/document could be used**

Receive documentation from them based on the academic degree or employment in the industry.

**From where data/document is obtainable**

Call this phone number: 00989124195752

**What processes are involved for a request to access data/document**

After the accuracy of the submitted documents, the data will be sent within a maximum of 2 weeks.

**Comments**