

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of ginger on prevention of headache and shivering after spinal anesthesia in patients with cesarean section referred to Kamali hospital in Karaj, 2016

#### Protocol summary

##### Study aim

Determine the effect of ginger on prevention of headache and shivering after spinal anesthesia in cesarean section

##### Design

This is a clinical trial study, randomized, open blindness, based on a specific group, Intervention with parallel groups, and trial phase 2, carried out with 170 sample size.

##### Settings and conduct

This study was carried out as a parallel clinical trial without blinding in Kamali hospital in Karaj. Sampling was done using simple random allocation.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 20 to 40 years 2.term pregnancy (42-37 weeks) and single Pregnant women who candidate for elective cesarean section; ASA class 1,2 .3 - Receiving written consent from patients. 4. No history of psychiatric problems. 5. Absence of hypothyroidism. 6. Failure to have meningitis at the time of study. 7. the lack of migraine. 8. the lack of record seizure or headache. 9. Start a headache within 72 hours. First cesarean section after spinal anesthesia. 10- the lack of Pre-eclampsia or eclampsia. Exclusion criteria: 1-unwillingness for participating in the study at each stage 2- cesarean section that lasts more than an hour 3- Fevered patients or unstable vital signs 4.history of psychotropic or opium drugs consumption 5. alcohol or drug abuse 6. Drug sensitivity

##### Intervention groups

Intervention group: Ginger 8 hours before spinal anesthesia and 8 hours after that, TDS (three times daily) until shivering. Control group: did not use pre-medication ginger, and only headache treatment with novafen and treatment of chills with meperidine

##### Main outcome variables

Post anesthesia shivering(PAS), Post dural puncture

headache(PDPH)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180110038302N1**

Registration date: **2018-04-29, 1397/02/09**

Registration timing: **retrospective**

Last update: **2018-04-29, 1397/02/09**

Update count: **0**

##### Registration date

2018-04-29, 1397/02/09

##### 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

2017-05-21, 1396/02/31

##### Expected recruitment end date

2018-03-22, 1397/01/02

##### Actual recruitment start date

2017-06-21, 1396/03/31

##### Actual recruitment end date

2018-04-20, 1397/01/31

### **Trial completion date**

empty

### **Scientific title**

The Effect of ginger on prevention of headache and shivering after spinal anesthesia in patients with cesarean section referred to Kamali hospital in Karaj, 2016

### **Public title**

The effect of ginger on headache and shivering after spinal anesthesia in patients with cesarean section

### **Purpose**

Other

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Inclusion criteria:1- Age of 20 to 40 years 2. pregnancy (37-42 weeks) and single Pregnant women who candidate for elective cesarean section; ASA class 1,2 .3 - Receiving written consent from patients. 4. No history of psychiatric problems. 5. Absence of hypothyroidism. 6. No meningitis at the time of study. 7. No migraine. 8. No seizure or headache. 9. Start a headache within first 72 hours after spinal anesthesia. 10- No Pre-eclampsia or eclampsia.

#### **Exclusion criteria:**

Exclusion criteria: 1-unwillingness for participating in the study at each stage 2- cesarean section that lasts more than an hour 3- Fevered patients or unstable vital signs 4.history of psychotropic or opium drugs consumption 5. alcohol or drug abuse 6. Drug sensitivity

### **Age**

From **20 years** old to **40 years** old

### **Gender**

Female

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **170**

Actual sample size reached: **160**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Firstly, a list of women from Cesarean section was prepared weekly. Then they were contacted with each one and the purpose and method of the study were explained. A written consent was obtained from women eligible to enter the study and each person was given an ID. Then, a simple random allocation was performed based on table of random numbers. Beginning, direction of numbers were determinate from top to bottom of table of random numbers. Based on the direction of the top-down table, the even numbers were selected for the intervention group and the odd numbers for the control group. These numbers were recorded on a sheet and allocated to the intervention and control groups. This process were continued until the sample size (170) was completed. Thus, two groups, each with 85 participants were formed.

### **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**

Alborz University of Medical Science

##### **Street address**

No.1, Eshteraki Blvd, Baghestan street, school of nursing And midwifery, karaj, Iran

##### **City**

karaj

##### **Province**

Alborz

##### **Postal code**

561-31452

#### **Approval date**

2017-06-20, 1396/03/30

#### **Ethics committee reference number**

ABZUMS.REC 1396.7

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Post Anesthesia Shivering(PAS), Post dural puncture headache(PDPH)

#### **ICD-10 code**

#### **ICD-10 code description**

### 2

#### **Description of health condition studied**

Complications of spinal anesthesia

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

Headache Intensity

#### **Timepoint**

From 24 hours before cesarean section every 8 hours and continue after cesarean section until headache

#### **Method of measurement**

Visual analog scale(VAS) ( 0 -10) was used to measure

the severity of headache.

## Secondary outcomes

### 1

#### Description

Shivering intensity

#### Timepoint

1, 3, 12 and 72 hours after cesarean

#### Method of measurement

Crossover-Mahajan criterion for measuring shivering (from 0 to 4)

## Intervention groups

### 1

#### Description

"In the intervention group" 24 hours before cesarean section, ginger capsule was prescribed 250 mg every 8 hours. After cesarean section, prescriptions for capsules continued before headache. In the event of headache, intervention was discontinued and routine headache treatment was used.

#### Category

Prevention

### 2

#### Description

"Control group": No intervention in control group.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kamali hospital

##### Full name of responsible person

Dr. Mansoureh Yazdkhshti

##### Street address

Karaj-Baghestan- Southern Common Blvd.-Alborz  
Nursing-Midwifery Faculty

##### City

Karj

##### Province

Alborz

##### Postal code

1829346253

##### Phone

+98 26 3430 4499

##### Email

Mansoyazd@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Karaj University of Medical Sciences

##### Full name of responsible person

Dr. Mansoureh Yazdkhshti

##### Street address

Karaj-Baghestan- Southern Common Blvd.-Alborz  
Nursing-Midwifery Faculty

##### City

Karj

##### Province

Alborz

##### Postal code

1829346253

##### Phone

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##### 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

Karaj 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

Karaj University of Medical Sciences

##### Full name of responsible person

Mansoureh Yazdkhshti

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Reproductive Health

##### Street address

Karaj-Baghestan- Southern Common Blvd.-Alborz  
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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Banafsheh Mushak

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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Karaj - Shahid Beheshti Avenue - Kamali Hospital  
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**Person responsible for updating data****Contact****Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Karaj-Baghestan- Southern Common Blvd.-Alborz  
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**City**

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**Province**

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**Postal code**

1829346253

**Phone**

+98 26 3430 4499

**Email**

Mansoyazd@yahoo.com

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available