

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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

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Karaj-Baghestan- Southern Common Blvd.-Alborz
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

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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

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

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Specialist

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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