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_ POWER 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

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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
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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
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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
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Other areas of specialty/work
Midwifery
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Person responsible for scientific

inquiries

Contact

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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

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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