Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of oral magnesium versus placebo on prevention of spinal anesthesia-induced headache after spinal anesthesia in women who undergo cesarean section: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of oral magnesium versus placebo on prevention of spinal anesthesia-induced headache after spinal anesthesia in women who undergo cesarean section

Design

This is a double-blind randomized clinical trial, phase II, in which 92 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients who are candidate for cesarean section and will refer to Fatemieh Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 15 to 45 years Candidate for sectarian under spinal anesthesia Exclusion criteria: History of migraine or headache Severe preeclampsia Sensitivity of magnesium

Intervention groups

Intervention group: A magnesium sachet of 300 magnesium is poured onto the patient's tongue 2 hours before surgery Control group: A magnesium sachet of 300 starch is poured onto the patient's tongue 2 hours before surgery

Main outcome variables

Primary outcome: Assessing the headache on the first, second and third days after the surgery using a visual analog scale (VAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N289**
Registration date: **2019-08-05, 1398/05/14**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-05, 1398/05/14**
Update count: **0**

Registration date

2019-08-05, 1398/05/14

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effects of oral magnesium versus placebo on prevention of spinal anesthesia-induced headache after spinal anesthesia in women who undergo cesarean section: a double-blind randomized clinical trial

Public title
Effects of oral magnesium versus placebo on prevention of spinal anesthesia-induced headache after spinal anesthesia in women who undergo cesarean section

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 15 to 45 years Candidate for sectarian under spinal anesthesia
Exclusion criteria:
History of migraine or headache Severe preeclampsia Sensitivity of magnesium

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Postal code
6517838695

Approval date
2019-04-27, 1398/02/07

Ethics committee reference number
IR.UMSHA.REC.1398.029

Health conditions studied

1

Description of health condition studied
Headache

ICD-10 code
G44

ICD-10 code description
Other headache syndromes

Primary outcomes

1

Description
Assessing the headache

Timepoint
On the first, second and third days after the surgery

Method of measurement
Using visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A magnesium sachet of 300 magnesium is poured onto the patient's tongue 2 hours before surgery

Category

Treatment - Drugs

2

Description
Control group: A magnesium sachet of 300 starch is poured onto the patient's tongue 2 hours before surgery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital in Hamadan City
Full name of responsible person
Maryam Sanatkar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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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
Hamedan 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
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Latest degree
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Person responsible for updating data

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Full name of responsible person
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Professor of Epidemiology

Latest degree
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Other areas of specialty/work
Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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