

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Fatemeh 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)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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

##### City

Hamadan

##### Province

Hamadan

##### 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

**Street address**

Fatemieh Hospital, Pasdaran Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3828 3939

**Email**

reihan20m@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

info.research@umsha.ac.ir

**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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Maryam Sanatkar

**Position**

Medical Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Fatemieh Hospital, Pasdaran Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3828 3939

**Email**

reihan20m@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Mahshid Nikooseresht

**Position**

Anesthesiologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Fatemieh Hospital, Pasdaran Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3828 3939

**Email**

nikoo\_mahshid@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

### Email

poorolajal@umsha.ac.ir

## 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