

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of oral magnesium sachet versus placebo on shivering after cesarean section under spinal anesthesia: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of oral magnesium sachet versus placebo on shivering after cesarean section under spinal anesthesia

Design

This is a double-blind randomized clinical trial, phase II, in which 50 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients who are candidates for elective cesarean section referring to the 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 examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 40 years, Women candidate for elective cesarean section, Exclusion criteria: Temperature less than 36.5 or greater than 38 centigrade, Duration of surgery longer than 180 minutes

Intervention groups

Intervention group: Oral magnesium sachet 300 mg (manufactured by Perarin Pars Co.) single dose half an hour before surgery Routine treatment plus Control group: Oral placebo sachet (including starch) single dose half an hour before surgery

Main outcome variables

Primary outcome: Shivering Secondary outcome: Nausea and vomiting, hypotension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N374**

Registration date: **2020-12-31, 1399/10/11**

Registration timing: **prospective**

Last update: **2020-12-31, 1399/10/11**

Update count: **0**

Registration date

2020-12-31, 1399/10/11

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

2021-01-14, 1399/10/25

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral magnesium sachet versus placebo on

shivering after cesarean section under spinal anesthesia:
a double-blind randomized clinical trial

Public title

Effect of oral magnesium sachet versus placebo on
shivering after cesarean section under spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 40 years, Women candidate for elective
cesarean section,

Exclusion criteria:

Temperature less than 36.5 or greater than 38
centigrade, Duration of surgery longer than 180 minutes

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

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

2020-12-21, 1399/10/01

Ethics committee reference number

IR.UMSHA.REC.1399.780

Health conditions studied

1

Description of health condition studied

Shivering

ICD-10 code

R25.1

ICD-10 code description

Tremor, unspecified

Primary outcomes

1

Description

Shivering

Timepoint

Every 15 minutes immediately after spinal anesthesia
until the presence of the patient in the recovery room

Method of measurement

By using a Bedside Four-Point Scale

Secondary outcomes

1

Description

Nausea and vomiting

Timepoint

During the presence of the patient in the recovery room

Method of measurement

By taking history and clinical observation

2

Description

Hypotension

Timepoint

Every 15 minutes immediately after spinal anesthesia until the presence of the patient in the recovery room

Method of measurement

By using sphygmometer

Intervention groups**1****Description**

Intervention group: Oral magnesium sachet 300 mg (manufactured by Perarin Pars Co.) single dose half an hour before surgery Routine treatment plus

Category

Treatment - Drugs

2**Description**

Control group: Oral placebo sachet (including starch) single dose half an hour before surgery

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Fatemieh Hospital in Hamadan city

Full name of responsible person

Yeganeh Sangian

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

yeganeh.sangian@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

Yeganeh Sangian

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

yeganeh.sangian@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

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

nikooseresht@umsha.ac.ir

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