

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of oral magnesium sachet versus placebo on treatment of post-dural puncture headache in pregnant women candidate for cesarean section: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of oral magnesium sachet versus placebo on treatment of post-dural puncture headache in pregnant women candidate for cesarean section

Design

This is a double-blind randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct

This study will be performed in the Fatemeh Hospital in Hamadan city on 130 eligible pregnant women candidate for cesarean section. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 15 to 45 years Pregnant women candidate for cesarean section Exclusion criteria: Preeclampsia History of chronic headache Renal failure

Intervention groups

Intervention group: Magnesium sachet 400 mg once a day for 3 days Control group: Placebo sachet once a day for 3 days

Main outcome variables

Primary outcome: Headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N433**

Registration date: **2022-07-06, 1401/04/15**

Registration timing: **prospective**

Last update: **2022-07-06, 1401/04/15**

Update count: **0**

Registration date

2022-07-06, 1401/04/15

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

2022-07-23, 1401/05/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral magnesium sachet versus placebo on treatment of post-dural puncture headache in pregnant women candidate for cesarean section: a double-blind randomized clinical trial

Public title

Effect of oral magnesium sachet versus placebo on treatment of post-dural puncture headache in pregnant

women candidate for cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 15 to 45 years Pregnant women candidate for cesarean section

Exclusion criteria:

Preeclampsia History of chronic headache Renal failure

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **130**

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

2022-06-25, 1401/04/04

Ethics committee reference number

IR.UMSHA.REC.1401.225

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

Headache

Timepoint

On the first, third and fifth days after cesarean section

Method of measurement

Using Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Magnesium sachet 400 mg once a day for 3 days

Category

Treatment - Drugs

2

Description

Control group: Placebo sachet once a day for 3 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Kamran Borhani Naeini

Street address

Fatemieh Hospital, Pasdaran Ave.

City

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6517838695

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+98 81 3838 0572

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kamranborhani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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

Hamedan University of Medical Sciences

Full name of responsible person

Kamran Borhani Naeini

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mahshid Nikooseresht

Position

Anesthesiologist

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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

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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