Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Fatemieh 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

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Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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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

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Province

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

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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
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Position
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Latest degree
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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