Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing Effect of Gabapentin and Caffeine on Treatment of Headache Following Spinal Anesthesia in Women Candidate for Cesarean Section

Protocol summary

Study aim
Comparing Effect of Gabapentin and Caffeine on Treatment of Headache Following Spinal Anesthesia in Women Candidate for Cesarean Section

Design
In this double-blind clinical trial, patients are assigned to the intervention and control groups by block random sampling.

Settings and conduct
Patients are not aware of the grouping and the study outcomes observed by a nurse who does not know the patient grouping and taking care of patients in the ward and recorded(outcomes) in the questionnaire. The site of this clinical trial is Besat Hospital in Sanandaj.

Participants/Inclusion and exclusion criteria
Being in level 1 and 2 of the ASA classification system, Incidence of post dural puncture headache, Elective cesarean section surgery,

Intervention groups
Intervention group 1: Administration of 300 mg of gabapentin orally every 12 hours for 3 days in patients after cesarean section with a history of post-dural puncture headache. Intervention group 2: Administration of 100 mg of caffeine orally every 12 hours for 3 days in patients after cesarean section with a history of post-dural puncture headache.

Main outcome variables
Headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210314050703N2**
Registration date: **2021-06-15, 1400/03/25**
Registration timing: **prospective**
Last update: **2021-06-15, 1400/03/25**
Update count: **0**

Registration date
2021-06-15, 1400/03/25

Registrant information

Name
Negin Ghadami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 87 3324 8519

Email address
ghadaminegin@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing Effect of Gabapentin and Caffeine on Treatment of Headache Following Spinal Anesthesia in Women Candidate for Cesarean Section

Public title
Comparing Effect of Gabapentin and Caffeine on Treatment of Headache Following Spinal Anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Being in level 1 and 2 of the ASA classification system Incidence of post dural puncture headache Elective cesarean section surgery
Exclusion criteria:
History of co-existing diseases such as asthma, cardiovascular disease, diabetes. History of caffeine or gabapentin allergy Need for other painkillers (such as acetaminophen) during the study period Preeclampsia and eclampsia History of chronic headaches and migraines

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are assigned to one of the intervention and control groups by block randomization method. In this method, how to randomize people to each of the intervention groups, the formation of 4 random blocks is used for randomization. The letter A is for group 1 (gabapentin) and the letter B is for group 2 (caffeine). The order of letters in each block is as follows. AABB, ABAB, ABBA, BBAA, BABA, BAAB Patients are assigned to one of the study groups based on the letters in each randomly selected block.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients do not know which study groups they will be in. Also, the nurse in the study provides the medication to the patients and is not aware of the patient's grouping. He/She also does not know which medication giving to the patient. Medications are coded by a nurse who does not participate in the study and provides the medication to the prescribing nurse based on the code. Also, the nurse who collects and records patient information does not know which group the patient belongs to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences

Street address
Pasdaran St., Kurdistan University of Medical Sciences

City
Sanandaj

Province
Kurdistan

Postal code
66177-13446

Approval date
2020-11-10, 1399/08/20

Ethics committee reference number
IR.MUK.REC.1399.202

Health conditions studied

1

Description of health condition studied
Post dural puncture headache

ICD-10 code
G44

ICD-10 code description
Other headache syndromes

Primary outcomes

1

Description
Headache

Timepoint
At intervals of 24, 48 and 72 hours after starting treatment

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Administration of 300 mg capsule of gabapentin(Mehr Darou- Tehran- Iran) orally every 12 hours for 3 days in patients after cesarean section with a history of post-dural puncture headache.

Category
Treatment - Drugs

2

Description
Intervention group 2: Administration of 100 mg capsule of caffeine (Weider - Canada) orally every 12 hours for 3 days in patients after cesarean section with a history of post-dural puncture headache.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Negin Ghadami
Street address
Mardokh south Street- Keshavarz St.
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6618634683
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besathospital@muk.ac.ir
Web page address
https://muk.ac.ir/Page?pageId=15

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Afshin Maleki
Street address
Faculty of Medicine, Kurdistan University of Medical Sciences, Pasdaran Blvd.
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Phone
+98 87 3366 4351
Email
Research@muk.ac.ir
Web page address
https://research.muk.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
Negin Ghadami
Position
Specialist
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Part of data on the primary outcomes will be shared.
When the data will become available and for how long
Six months after the publication of the results data access is possible.
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
Meta-analysis is allowed.
From where data/document is obtainable
Dr. Negin Ghadami via Email: ghadaminegin@gmail.com
What processes are involved for a request to access data/document
Three months after the request, the data will be sent.
Comments