# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Preventive effect of cyproheptadine in preventing headache and hypotension in spinal anesthesia in patients undergoing spinal anesthesia

## Protocol summary

**Study aim**
Determination of the preventive effect of cyproheptadine in preventing headache and hypotension in spinal anesthesia

**Design**
A single-blind control clinical trial with parallel and randomized groups sealed by the envelope will be performed on 56 patients in Phase 2.

**Settings and conduct**
In the current interventinal study, which Will be carried out as a single-blind clinical trial, 56 patients undergoing spinal anesthesia at Khatam Al-Anbia Hospital in Shahroud in 1400 and 1401 will be randomly selected. Individuals are randomly divided into one of two groups receiving ciproheptadine (4 mg single dose) or placebo (single-dose ciproheptadine placebo tablets). Follow-up in the field of headache and hypotension will be done for 24 to 48 hours after the operation and the frequency of headache and hypotension in the two groups will be determined.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: surgery under spinal anesthesia, elective surgery, and American Society of Anesthesiologists (ASA) class I. Exclusion criteria: unwillingness of patients to cooperate, underlying diseases, and emergency surgeries.

**Intervention groups**
The intervention groups included the ciproheptadine group (receiving ciproheptadine tablets at a dose of 4 mg as a single oral dose) and the placebo group (receiving a single-dose placebo ciproheptadine tablet).

**Main outcome variables**
Headache and hypotension

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20211218053439N1**
Registration date: **2022-02-22, 1400/12/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-22, 1400/12/03**
Update count: **0**

**Registration date**
2022-02-22, 1400/12/03

**Registrant information**

**Name**
Zahra Farhadi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-02-20, 1400/12/01

**Expected recruitment end date**
2022-07-23, 1401/05/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Preventive effect of cyproheptadine in preventing

headache and hypotension in spinal anesthesia in patients undergoing spinal anesthesia

**Public title**
Effect of cyproheptadine on headache and hypotension after spinal anesthesia

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Surgery under spinal anesthesia Elective surgery American Society of Anesthesiologists(ASA) class I Age between 20 and 70 years

**Exclusion criteria:**
Reluctance to participate in the study Having any underlying disease Emergency surgery

**Age**
From **20 years** old to **70 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **56**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Our aim is to categorize the subjects in two separate groups; A(cyproheptadine) and B(control). To achieve this goal, 4 blocks Will be randomly chosen; AABB, BABA, BAAB, BBAA, which will each be put in a packet afterwards, so that selection of each packet is equally random. For the first 4 participants a block will randomly chosen and selection of the remaining will follow the rule.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
The participants, who are fully informed about the study, will not be cognisant of whether they are receiving cyproheptadine or placebo, whereas the research crew including the physician, the nurse, the person responsible for collecting data, the researcher, and the person preparing the draft article and the Safety and Data Monitoring Committee will be aware of the type of medication applied. It is worth mentioning that we will use placebo for blinding in this study. The placebo will be prepared exactly the same as the main drug(cyproheptadine) in terms of both colour and shape, with the cooperation of one of the pharmacy universities. Afterwards, they will be given to the participants.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Research Ethics Committees of Islamic Azad University - Shahrood Branch

**Street address**
Islamic Azad University of Shahroud, University Blvd., Shahroud

**City**
Shahrood

**Province**
Semnan

**Postal code**
3619943189

**Approval date**
2021-02-06, 1399/11/18

**Ethics committee reference number**
IR.IAU.SHAHROOD.REC.1399.077

## Health conditions studied

### 1

**Description of health condition studied**
Spinal anesthesia induced headache and hypotension

**ICD-10 code**
-

**ICD-10 code description**
-

## Primary outcomes

### 1

**Description**
Spinal anesthesia-induced headache

**Timepoint**
Evaluation of headache at the beginning of the study (before surgery) and 24 and 48 hours after surgery

**Method of measurement**
Through questionnaire

### 2

**Description**
Spinal anesthesia-induced hypotension

**Timepoint**
Measurement of blood pressure at the beginning of the study (before surgery) and 24 and 48 hours after surgery

**Method of measurement**
Blood pressure monitoring

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Receiving cyproheptadine tablets with a dose of 4 mg and single dose orally
**Category**
Treatment - Drugs

**2**

**Description**
Control group: receiving single-dose ciproheptadine placebo tablets orally
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Khatam Al-Anbia Hospital
**Full name of responsible person**
Yosef Kolokhi
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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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**
Islamic Azad University
**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**
Islamic Azad University
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Zahra Farhadi
**Position**
Medical Student
**Latest degree**
A Level or less
**Other areas of specialty/work**
General Practitioner
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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**
Not applicable