

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 interventional 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 cyproheptadine (4 mg single dose) or placebo (single-dose cyproheptadine 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 cyproheptadine group (receiving cyproheptadine tablets at a dose of 4 mg as a single oral dose) and the placebo group (receiving a single-dose placebo cyproheptadine 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)

##### Phone

+98 23 3220 1378

##### Email address

safa75967596@gmail.com

##### 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 Shahrood, University Blvd., Shahrood

##### 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

#### Street address

Khatam Al-Anbia Hospital, University Blvd

#### City

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#### Province

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#### Postal code

3614871151

#### Phone

+98 23 3222 7087

#### Email

dryousefkolookhianestezi@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Behroz Yahyali

#### Street address

Islamic Azad University of Shahrood, University Blvd

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#### Province

Semnan

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36199-43189

#### Phone

+98 23 3220 1452

#### Email

sabafarhadi9675@gmail.com

#### 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

#### Full name of responsible person

Zahra Farhadi

#### Position

Medical Student

#### Latest degree

A Level or less

#### Other areas of specialty/work

General Practitioner

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Yosef Kolokhi

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Anesthesiology

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Zahra Farhadi

**Position**

Medical Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Islamic Azad University of Shahroud, University Blvd

**City**

Shahrood

**Province**

Semnan

**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