

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of atropine on prevention of vasovagal syncope before spinal anesthesia

#### Protocol summary

##### Study aim

Because vasovagal shock can occur as a result of seeing unpleasant scenes and the patient falls heavily on the ground and suffers physical injury and, on the other hand, with severe cardiac arrest and slowing heart rate has unpleasant consequences for the heart, it is controlled. Can be helpful.

##### Design

A randomized, double-blind, placebo-controlled clinical trial

##### Settings and conduct

This study is a double blind clinical trial that will be conducted in Khatam Al-Anbia Hospital of Shahroud in 1389-99.

##### Participants/Inclusion and exclusion criteria

conditions for entering: Patient's informed consent to participate in the study ASA II,III Female or male aged 15 to 60 years conditions for exiting: People's unwillingness to participate in the study History of heart disease History of hypertension medications such as propranolol History of cigarette alcohol abuse and any drug abuse History of neurological disease

##### Intervention groups

It is designed to evaluate the prophylactic effect of atropine from vasovagal syncope before spinal anesthesia.

##### Main outcome variables

1. Determination of the association between vasovagal syncope and atropine injection in pre-regional anesthesia by age
2. Determination of the association between vasovagal syncope and atropine injection in pre-regional anesthesia by sex
3. Determination of the association between vasovagal syncope and atropine injection in pre-regional weight loss stage
- 4- Determination of the association between vasovagal syncope and atropine injection in pre-regional anesthesia according to blood pressure
5. Determination of the association between vasovagal syncope and atropine injection in pre-regional anesthesia in terms of phlebotomy rate
6. Determine the

relationship between people's extreme fear of needles and the occurrence of vasovagal syncope

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191231045957N1**

Registration date: **2020-02-29, 1398/12/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-29, 1398/12/10**

Update count: **0**

##### Registration date

2020-02-29, 1398/12/10

##### Registrant information

##### Name

Nazanin Golalizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 4269 1573

##### Email address

nazanin.glz7474@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-12-20, 1399/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of atropine on prevention of vasovagal syncope before spinal anesthesia

**Public title**

The effect of atropine on prevention of vasovagal syncope

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patient's informed consent to participate in the study ASAll,III Female or male aged 15 to 60 years

**Exclusion criteria:**

People's unwillingness to participate in the study History of heart disease History of hypertension medications such as propranolol History of cigarette alcohol abuse and any drug abuse History of neurological disease

**Age**

From **15 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

We explain and consent to this intervention for the patient. But we don't talk to the patient about injecting placebo.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad University Shahrood Branch

**Street address**

Semnan, Shahrood, Islamic Azad University, Central dormitory, next to the gas station

**City**

shahrood

**Province**

Semnan

**Postal code**

4318936199

**Approval date**

2019-12-14, 1398/09/23

**Ethics committee reference number**

IR.IAU.SHAHROOD.REC.1398.036

**Health conditions studied****1****Description of health condition studied**

effect of atropine on prevention of vasovagal syncope

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Atropine

**Timepoint**

Before the intervention, 15 minutes after the intervention and one hour after the intervention

**Method of measurement**

Milligram and questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Bupivacaine Half Percent Spinal For Spinal Anesthesia. Atropine sulfate 0.5 mg drug from Tehran-Iran Pharmaceutical Manufacturing Company (IRC): 0931701432667660 We will use for the present study.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Khatam ol Anbia Hospital

**Full name of responsible person**

Yahyaii Behrouz

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next to the gas station, Central dormitory, Islamic Azad University, Shahrood, ,Semnan

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
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Dr. yahyaii.Behrouz  
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**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor  
organization/entity?**  
No  
**Title of funding source**  
researcher  
**Proportion provided by this source**  
100  
**Public or private sector**  
Private  
**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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Dr.Yahyaii.Behrouz  
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medical student  
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A Level or less  
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General Practitioner  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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Medical student  
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

empty

**When the data will become available and for how long**

empty

**To whom data/document is available**

empty

**Under which criteria data/document could be used**

empty

**From where data/document is obtainable**

empty

**What processes are involved for a request to access data/document**

empty

**Comments**