Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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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 ASAII,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, Shahroud, 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, Shahroud, ,Semnan

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Sponsors / Funding sources

1

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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
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Latest degree
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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