

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Comparison the effect of stretching exercises and caffeine tablets on reducing headache after spinal anesthesia

#### Protocol summary

##### Study aim

Evaluation of the concurrent effect of stretching exercises and caffeine tablets on reducing headache after spinal anesthesia

##### Design

Patient candidate for varicocele surgery or hernia repair, randomly and with using table of random number are in 4 groups and each group contain 39 individuals. Groups; caffeine's group , stretching exercise's group , caffeine and stretching exercise's group and control's group. Sample size 156 was determined that divided in 4 groups. Clinical trial , single blind , with control group

##### Settings and conduct

patients candidate varicocele surgery or hernia repair in Shahid Modares hospital that receive spinal anesthesia with marcaine divided in groups and participants have no information about groups and receiving medication or placebo.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria All patient between 20 to 60 years old Candidate of varicocele surgery or hernia repair Without caffeine allergy Exclusion criteria History of hypertension and cardiac disease

##### Intervention groups

four groups ; First group receive oral tablet caffeine 200 mg Second group only do stretching exercises Third group receive oral tablet caffeine 200 mg and exercise Fourth group (controlled group) receive Placebo tablet

##### Main outcome variables

Effect of caffeine on headache severity as one of the common post spinal complications.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190131042569N1**

Registration date: **2020-01-19, 1398/10/29**

Registration timing: **retrospective**

Last update: **2020-01-19, 1398/10/29**

Update count: **0**

##### Registration date

2020-01-19, 1398/10/29

##### Registrant information

###### Name

Nima saeedi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2641 8939

###### Email address

nimasaeedi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-17, 1397/12/26

##### Expected recruitment end date

2019-07-17, 1398/04/26

##### Actual recruitment start date

2019-03-17, 1397/12/26

##### Actual recruitment end date

2019-08-17, 1398/05/26

##### Trial completion date

2020-03-16, 1398/12/26

##### Scientific title

Comparison the effect of stretching exercises and caffeine tablets on reducing headache after spinal anesthesia

##### Public title

The effect of stretching exercises and caffeine tablets on headache after spinal anesthesia

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All the patient between 20 to 60 years old Candidate for varicocele surgery or hernia repair Without caffeine allergy

### Exclusion criteria:

History of hypertension or cardiac disease

## Age

From **20 years** old to **60 years** old

## Gender

Male

## Phase

3

## Groups that have been masked

- Care provider
- Outcome assessor

## Sample size

Target sample size: **156**

Actual sample size reached: **156**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Each patient who qualifies for inclusion after completing the consent form is assigned by the person in charge of this process using a random number table from 1 to 156( 1- 39 caffeine group , 40-78 stretching exercise group , 79-117 caffeine and stretching exercise group and 118 -156 control group)where the person is placed on one of the numbers and assigned to one of the 4 specified groups. (Simple randomization by individual using random number table)

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The anesthesiologist in charge of spinal anesthesia is not aware of the patient's group (intervention or control groups), whom receive anesthesia. and the person responsible for follow-up, patient, contact to patients and recordings data and pain levels has o information about the intervention or control group. and only one person responsible for giving the patient's drug or placebo and how to perform the stretching exercise is aware of the patient groups.

## Placebo

Used

## Assignment

Factorial

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

## Name of ethics committee

Ethics committee Shahid Beheshti University of Medical Sciences

## Street address

Shahid Beheshti University of Medical Science, Arabi Ave , Daneshjoo Blvd ,Velenjak , Tehran

## City

Tehran

## Province

Tehran

## Postal code

1985717443

## Approval date

2019-03-17, 1397/12/26

## Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1389

## Health conditions studied

### 1

#### Description of health condition studied

Post spinal headache

#### ICD-10 code

O89.4

#### ICD-10 code description

Spinal and epidural anesthesia-induced headache during the puerperium

## Primary outcomes

### 1

#### Description

The effect of stretching exercises and caffeine on post spinal headache

#### Timepoint

every 6 h in first 48 h , 3rd day and 5th day after the procedure

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group1: Caffeine group(caffeine tablet 200 mg Karen Company , once a day at morning for 1 week)

#### Category

Prevention

### 2

#### Description

Intervention group2: Stretching exercise's group( Stretching exercise 20 minute , once a day at morning for 1 week)

**Category**

Prevention

**3****Description**

Intervention group3: Caffeine(caffeine tablet 200 mg Karen Company , once a day at morning) and Stretching exercise's group( Stretching exercise 20 minute , once a day at morning for 1 week )

**Category**

Prevention

**4****Description**

Control group: Placebo

**Category**

Placebo

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

Shahid Modares Hospital

**Full name of responsible person**

Niloufar massoudi

**Street address**

Shahid Modares Hospital , Saadat abad boulevard

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Research Department of Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Ali Ziayi

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Third floor, School of Medicine , near the Taleghani Hospital , Evin , Shahid Chamran Highway

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**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Department of Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Niloufar Massoudi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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nimasaeedi7@yahoo.com

## 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

Participant data (age, pain severity and type of patient's group) are to be shared.

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

1 year after publication

### To whom data/document is available

Researchers working in academic institutions

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

Using data and analysis for use in academic research

### From where data/document is obtainable

Send Email Dr.Nima Saeedi Email Address:  
nimasaeedi7@yahoo.com

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

Send request via Email and after 1 week will be replied.

### Comments