

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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

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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

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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

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Person responsible for updating data

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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

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