

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of adrenocorticotropin and aminophylline and caffeine; On the treatment of headache after tearing in patients with spinal anesthesia.

Protocol summary

Study aim

Evaluation the effectiveness of adrenocorticotropine and aminophylline in comparison with caffeine in treatment of headache after dural puncture .

Design

Clinical trials with control group, with parallel groups, randomized in 90 patients.

Settings and conduct

Clinical trial, Ayatollah Mousavi Hospital, Zanjan, Iran

Participants/Inclusion and exclusion criteria

Participants aged 18 to 45 years with a headache that improves with sleep, no contraindication of steroid therapy and absence of migraine headache, have the entry requirements for the study. Participants are excluded from the study with dissatisfaction, history of cardiac arrhythmias and drugs allergy.

Intervention groups

Female patients aged 18-45 years who have a headache after spinal anesthesia for cesarean section and have criteria for entering the study, will be divided into three groups using randomized blocked random sampling. The first group of caffeine tablets 300 mg twice a day, the second group of muscle ACTH injections, and the third group of aminophylline ampoules 250 mg per 100 ml of normal saline will be given in half an hour. The patient's VAS will be measured before intervention, as well as at hours 1, 6, 12, 24, and 48 after intervention. Within 48 hours after the intervention, if the patient complains of headache failure and their VAS is greater than or equal to 4, additional accommodation will be prescribed. Satisfaction will also be measured. The need for admission and epidural epidural blood patch is recorded and compared among all three groups

Main outcome variables

Headache severity, satisfaction of patients, need for additional analgesic up to 48 hours after treatment

General information

Reason for update

Acronym

PDPH

IRCT registration information

IRCT registration number: **IRCT20180325039148N4**

Registration date: **2019-11-05, 1398/08/14**

Registration timing: **prospective**

Last update: **2019-11-05, 1398/08/14**

Update count: **0**

Registration date

2019-11-05, 1398/08/14

Registrant information

Name

Saeed Jalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 0001

Email address

jalilis45@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of adrenocorticotropin and aminophylline and caffeine; On the treatment of headache after tearing in patients with spinal anesthesia.

Public title
"Effect of caffeine, aminophylline and adrenocorticotropin on headache after spinal anesthesia"

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
positional Headache that is aggravated by lying down and exacerbate by sitting and standing lack of steroid contraindication including: hypertension, diabetes No drug or any other palliative during surgery No history of migraine or psychotic and neurological disease No history of caffeine allergy
Exclusion criteria:
Patient dissatisfaction Heart arrhythmias

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences
Street address
Mousavi Hosp. , Gavazang Blvd.
City
Zanjan
Province

Zanjan
Postal code
4513956183
Approval date
2018-10-16, 1397/07/24
Ethics committee reference number
IR.ZUMS.REC.1397.186

Health conditions studied

1

Description of health condition studied
postdural puncture headache post cesarean section
ICD-10 code
O89.4
ICD-10 code description
Spinal and epidural anaesthesia-induced headache during the puerperium

Primary outcomes

1

Description
Headache severity scale in VAS
Timepoint
At 0,1,6,12,24,48 hours intervals
Method of measurement
Visual Analog Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Caffeine tablets 300 mg twice a day
Category
Treatment - Drugs

2

Description
Intervention group: 1 mg ACTH (synacthen, Iran hormones) intramuscular injection
Category
Treatment - Drugs

3

Description
Intervention group: Aminophylline Ampoules 250 mg (Sina Daru) Inside 100 ml normal
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Moosavi Hospital

Full name of responsible person

Saeed Jalili

Street address

Moosavi Hosp. ,Gavazang Blvd.

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Web page address

http://zums.ac.ir/index.php?slc_lang=fa&sid=19

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Shoghli Alireza

Street address

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

Yes

Title of funding source

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Saeed Jalili

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Saeed Jalili

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available