

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Evaluation of the effect of intravenous Aminophylline on prevention of headache after spinal anesthesia in patients undergoing elective cesarean section

Protocol summary

Study aim

Effect of intravenous aminophylline on headache after spinal anesthesia in patients undergoing elective cesarean section

Design

Non randomized clinical trial with control group, parallel groups, double blind

Settings and conduct

The study will be performed at Valiasr Hospital in Birjand. All patients will be randomly divided into two groups of Bupivacaine and Aminophylline recipients and Bupivacaine and dextrose water 5% recipients. While the surgeon and the patient are unaware of the type of injection solution, the injection will be performed by the resident or anesthesia technician. Designer who is completely unaware of injectable drugs will perform all post-injection evaluations.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged 15-45 years with term pregnancy; candidate for elective cesarean section. Non inclusion criteria: Women with known allergies to amide drugs; Women who have spinal anesthesia contraindications; Women with a history of chronic headaches.

Intervention groups

The intervention group: Bupivacaine and aminophylline recipients receiving 15mg bupivacaine 0.5% and 1.5mg / kg intravenous aminophylline. The control group: receiving bupivacaine and dextrose water 5%

Main outcome variables

Headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190413043254N1**

Registration date: **2020-01-08, 1398/10/18**

Registration timing: **retrospective**

Last update: **2020-01-08, 1398/10/18**

Update count: **0**

Registration date

2020-01-08, 1398/10/18

Registrant information

Name

Atefeh Yari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4645 3283

Email address

atefeh.yari.1995@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-06, 1398/01/17

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of intravenous Aminophylline on prevention of headache after spinal anesthesia in patients undergoing elective cesarean section

Public title

The effect of Aminophylline on post-cesarean headache

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Women who are able to contribute to the project Women who are candidates for elective cesarean section Women being at the age of 15 to 45 years old

Exclusion criteria:

Women with chronic headache history Women who have coagulopathy or infectious heart disease Women who have a history of drug abuse Women with history of using psychotropic drugs Women who have contraindications for spinal anesthesia, such as high levels of intracranial pressure and lack of satisfaction. Women who have a known sensitivity to amid drugs

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Not randomized

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

Double blinded

Blinding description

While the surgeon and the patient are unaware of the type of injection solution, the injection will be performed by the resident or anesthesia technician. Designer who is completely unaware of injectable drugs will perform all post-injection evaluations.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Birjand University of Medical Sciences

Street address

Moallem Avenue

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2018-12-19, 1397/09/28

Ethics committee reference number

IR.BUMS.REC.1397.242

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

postdural puncture headache

ICD-10 code

G44

ICD-10 code description

Other headache syndromes

Primary outcomes**1****Description**

Headache

Timepoint

1, 8, 16, 24, 36 and 48 hours after surgery

Method of measurement

Headache questionnaire

Secondary outcomes

empty

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

Intervention group: Patients in this group will receive 15 mg of Bupivacaine 0.5% and 250 CC of Dextrose water 5% containing 1.5 mg / kg intravenous Aminophylline.

Category

Prevention

2**Description**

Control group: Patients in this group will receive 15 mg of Bupivacaine 0.5% and 250 cc of Dextrose water 5%.

Category

Placebo

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

Birjand Valiasr hospital

Full name of responsible person

Atefeh Yari

Street address

No 73; Hafez 6.1; Hafez avenue; Birjand city

City

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Province

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Postal code

9717853577

Phone

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Email

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Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

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

Birjand University of Medical Sciences

Full name of responsible person

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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

Birjand 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**

Birjand University of Medical Sciences

Full name of responsible person

Atefeh Yari

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Bibi Fatemeh Emampour

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Education

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Person responsible for updating data**Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Atefeh yari

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available