

# 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**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 51 4645 3283

**Email**

atefeh.yari.1995@gmail.com

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Education

**Street address**

No 73; Hafez 6.1; Hafez avenue; Birjand city

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**Province**

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**Email**

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

Birjand University of Medical Sciences

**Full name of responsible person**

Atefeh Yari

**Street address**

No 73; Hafez 6.1; Hafez avenue; Birjand city

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Birjand

**Province**

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**Postal code**

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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

**Street address**

No 73; Hafez 6.1; Hafez avenue; Birjand city

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 51 4645 3283

**Email**

f.emampour@gmail.com

**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**

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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