

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of intravenous administration of Aminophylline on prevention of post spinal Anesthesia Headache in patients undergoing elective cesarean Section

Protocol summary

Summary

Background & Purpose: In this study the effect of intravenous administration of Aminophylline on prevention of post spinal headache was evaluated. Design of experiments: double blind clinical trial Methods: Patients randomly divided into 2 groups. Inclusion criteria: 140 patients candidate spinal anesthesia at the age of 18-35 and set in class I & II of Anesthesia Society of America (ASA) was selected. Exclusion criteria: Patients with history of cardiovascular disease, cerebral, Hypertension, Diabet mellitus, Preeclampsia, Seizure, Migrain, History of Post spinal anesthesia headache, Unwilling to spinal anesthesia to experience spinal anesthesia, coagulopathy, Psychiatry. Intervention: patients were randomly allocated into 2 groups receiving either 100 cc of normal saline or 1 mg/kg aminophylline dissolved in 100 cc of normal saline after delivery & cord clamping. 4, 8, 24, 48, 72 hours after operation the occurrence of headache was evaluated according to VAS score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411294923N6**
Registration date: **2015-01-08, 1393/10/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-08, 1393/10/18

Registrant information

Name

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Name of organization / entity

Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor Of Research Babol University Of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-07-21, 1394/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous administration of Aminophylline on prevention of post spinal Anesthesia Headache in patients undergoing elective cesarean Section

Public title

The effect of intravenous administration of Aminophylline on prevention of post spinal Anesthesia Headache in patients undergoing elective cesarean Section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients candidate for spinal anesthesia set in class I & II of Anesthesia Society of America (ASA) was selected, Exclusion criteria: Patients with history of cardiovascular disease, cerebral, Hypertention,Diabet mellitus, Preeclampsia, Seizure, Migrain, History of Post spinal anesthesia headache, Unwilling to spinal anesthesia to experience spinal anesthesia, coagulopathy,Psychiatry.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University Of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code

Approval date

2014-07-08, 1393/04/17

Ethics committee reference number

4323/30/پ/ز

Health conditions studied

1

Description of health condition studied

Post spinal anesthesia headache

ICD-10 code

G97.1

ICD-10 code description

Other reaction to spinal and lumbar puncture

Primary outcomes

1

Description

Post spinal anesthesia headache

Timepoint

4,8,24,48,72 hours after operation

Method of measurement

Score pain

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before and after spinal anesthesia and delivery and cord clamping and after drug injectionand then every 5 minutes until the end of operation

Method of measurement

Non- invasive manometer

2

Description

Heart rate

Timepoint

Before and after spinal anesthesia and delivery and cord clamping and after drug injectionand then every 5 minutes until the end of operation

Method of measurement

Heat rate monitoring

Intervention groups

1

Description

Prevention group: Intravenous injection of aminophylline 1 mg/kg in 100 cc normal saline

Category

Prevention

2

Description

Control group: injection of 100 cc normal saline

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ruhani Hospital

Full name of responsible person

Dr bahman hasannasab

Street addressAnesthesiology Department, Ruhani Hospital,
Daneshgah Square, Ganjafrooz Avenue**City**

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Email

bahmanh2002@yahoo.com

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

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Full name of responsible person

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Position

Resident of Anesthesiology

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice-chancellor Of Research Babol University Of
Medical Sciences**Full name of responsible person**

Ali Akbar Moghadamnia

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

Yes

Title of funding sourceVice-chancellor Of Research Babol University Of Medical
Sciences**Proportion provided by this source**

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Dr Bahman Hasannasab

Position

Assistant Professor of Anesthesiology

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report**

empty
Analytic Code
empty

Data Dictionary
empty