Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of intravenous adminastration 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 recieving either 100 cc of normal salin or 1 mg/kg aminophylline dissolved in 100 cc of normal salin after delivery & cord clamping. 4,8,24,48,72 hours after operation the occurance 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

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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 adminastration of Aminophylline on prevention of post spinal Anesthesia Headache in patients undergoing elective cesarean Section

Public title

The effect of intravenous adminastration 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 desease, 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/ژ/پ

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 salin

Category
Prevention

2

Description
Control group: injection of 100 cc normal salin

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Ruhani Hospital

Full name of responsible person
Dr bahman hasannasab
Street address
Anesthesiology Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor Of Research Babol 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
Vice-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

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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