Clinical Trial Protocol
Iranian Registry of Clinical Trials
10 Oct 2022

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 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: empty
Update count: 0
Registration date 2015-01-08, 1393/10/18

Registrant information
Name Bahman Hasannasab

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, Hypertension, Diabetes mellitus, Pre-eclampsia, 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
Double blinded

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 injection and 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 injection and then every 5 minutes until the end of operation
Method of measurement
Heart 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
City Babol

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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Vice-chancellor Of Research, Daneshgh Square, Ganjafrooz Avenue
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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

Contact
Name of organization / entity
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Assistant Professor of Anesthesiology
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Person responsible for updating data

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Position
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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