Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The Efficacy of Prophylactic Intravenous Aminophylline, Paracetamol or Aminophylline and Paracetamol in Prevention of Post spinal headache in lower extremity surgeries Compared to the Control Group

Protocol summary

Study aim
Comparison of the effect of administration of aminophylline, paracetamol, aminophylline and paracetamol on prevention of headache after spinal anesthesia in lower limb surgery

Design
Clinical trials with control group, with randomized, double-blind, Non-random, controlled clinical trials

Settings and conduct
An Anesthetist nurse prepared the syringes containing the prescribed drugs or normal saline for the patient. All drugs were 5 ml in volume and patients received intravenous drug 15 minutes before surgery. The patients and the reviewer who collected the data were not aware of the random selection of the groups.

Participants/Inclusion and exclusion criteria
Criteria for entering the study:Age range of 20-50 years, candidate for lower extremity surgery, Normal blood pressure Criteria for not entering the study: Underlying disease, Migraine headache, Get analgesic 24 hours before surgery

Intervention groups
In the 4 groups of 30 patients, the patients in the first group received 1.5 mg / kg aminophylline, the second group received 1000 mg paracetamol, the patients in the third group received aminophylline and paracetamol with the same dose and the patients in the fourth group (control) received 100 cc normal saline.

Main outcome variables
Headache; nausea;

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190717044246N1**
Registration date: **2019-08-25, 1398/06/03**
Registration timing: **retrospective**

Last update: **2019-08-25, 1398/06/03**
Update count: **0**

Registration date
2019-08-25, 1398/06/03

Registrant information

Name
Somayeh Asadpoor

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3554 2381

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rahgozar.m.b@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-03-20, 1395/01/01

Expected recruitment end date
2018-02-20, 1396/12/01

Actual recruitment start date
2018-01-24, 1396/11/04

Actual recruitment end date
2018-03-11, 1396/12/20

Trial completion date
2019-02-20, 1397/12/01

Scientific title
The Efficacy of Prophylactic Intravenous Aminophylline, Paracetamol or Aminophylline and Paracetamol in Prevention of Post spinal headache in lower extremity surgeries Compared to the Control Group

Public title
The effect of aminophylline and paracetamol administration on headache
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age range of 20-50 years, candidate for lower extremity surgery Normal blood pressure
Exclusion criteria:
Migraine history Get analgesic 24 hours before surgery Underlying disease
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **120**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and clinicians are unaware of the type of injectable drug used to prevent headache after anesthesia.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Yaghoot Building, Saadat Ave, Hedayat St,
City
Isfahan
Province
Isfehan
Postal code
8198317919
Approval date
2018-01-23, 1396/11/03
Ethics committee reference number
IR.MUI.REC.1396.3.777

Health conditions studied

1

Description of health condition studied
Spinal Anesthesia
ICD-10 code
O74.6
ICD-10 code description
Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes

1

Description
Headache severity
Timepoint
Before the spinal anesthesia, 15 minutes before recovery, the first day every 6 hoursl and the first week daily
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
intervention group 1: 1.5 mg / kg aminophylline, intra venously, The drugs were injected 15 minutes before the end of surgery
Category
Prevention

2

Description
intervention group 2: 1000 mg paracetamol, intra venously, The drugs were injected 15 minutes before the end of surgery
Category
Prevention

3

Description
intervention group 3: aminophylline and paracetamol with similar dose, intra venously, The drugs were injected 15 minutes before the end of surgery
Category
Prevention

4

Description
Control group: received 100 ml normal saline, intra venously, The drugs were injected 15 minutes before the end of surgery
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Parviz Kashefi
Street address
Sofeh Boulevard - Al-Zahra Educational Center
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Fax
+98 31 3669 1510
Email
alzahra@mui.ac.ir
Web page address
http://alzahra.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoye Javanmard
Street address
No 4, Isfahan University of Medical science, Hezar jerib St
City
اصفهان
Province
Isfehan
Postal code
۷۳۴۶۱۸۱۷۴۶
Phone
+98 31 3668 8138
Fax
+98 31 3668 5149
Email
research@mui.ac.ir
Web page address
https://research.mui.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Somayeh Asadpoor
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Education
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Part of the data includes information of the main outcome as well as the results of study is possible to share.
When the data will become available and for how long
Since 2020
To whom data/document is available
Public access
Under which criteria data/document could be used
There are no special conditions
From where data/document is obtainable
No 25, Cyrus Building, Parvin St, Isfahan Phone number: 00983135553078 Mob: 00989131039912
What processes are involved for a request to access data/document
To receive the data, you must first submit a written request. After checking, within a maximum of one week, the documentation will be sent.
Comments