Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the efficacy of intravenous Caffeine versus intravenous Aminophylline in reduction of post-spinal anesthesia headache in cesarean sections in Amiralmomenin Hospital in 2013 and 2014

Protocol summary

Summary

Objectives: cesarean section is one of the most common surgical procedures in young women.cesarean section is performed in most cases with spinal anesthesia .one of the most important complications of spinal anesthesia is post dural puncture headache(PDPH). The aim of this study was to determine and comparing efficacy of intravenous Aminophylline versus intravenous Caffeine in reduction of post spinal anesthesia headache in cesarean section. Design: Randomized clinical trial, double blind, one center , phase ш clinical trial. Setting and conduct: In this randomized clinical trial , were enrolled 210 women under elective cesarean section in Amiralmomenin Hospital in Tehran in 2013 and 2014 Participants including major eligibility criteria: Inclusion:consent to participate in the study; elective cesarean section;ASA (American Society of Anesthesiologists)=1;lack of sensivity to Caffeine and Aminophylline;No history of headache. exclusive:The need for general anesthesia during surgery;opioide use during surgery. Intervention: Randomly assigned patients to receive either intravenous Aminophylline 1.5 mg.Kg and intravenous caffeine 30 mg plus 100cc normal saline. Variable: The frequency and severity of post spinal anesthesia headache were determined and compared by visual Analog Scale between two groups at the 4,24,48 hour after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030126865N1**
Registration date: **2016-05-14, 1395/02/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-14, 1395/02/25

Registrant information

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Fereshteh Odar
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Recruitment status

Recruitment complete

Funding source

Islamic Azad University Tehran Medical Science branch

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of intravenous Caffeine versus intravenous Aminophylline in reduction of post-spinal anesthesia headache in cesarean sections in Amiralmomenin Hospital in 2013 and 2014

Public title

Comparing the efficacy of intravenous Caffeine versus intravenous Aminophylline in reduction of post-spinal anesthesia headache in cesarean sections

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: consent to participate in the study; elective cesarean section; ASA (American Society of Anesthesiologists)=1; lack of sensivity to Caffeine and Aminophylline; No history of headache exclusive: The need for general anesthesia during surgery; opioide use during surgery

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Islamic Azad University Tehran Medical Science branch

Street address

KHaghani St, SHariati St, Tehran

City

Tehran

Postal code

Approval date

2015-03-01, 1393/12/10

Ethics committee reference number

IR.IAU.TMU.REC.1394.74

Health conditions studied

1

Description of health condition studied

Post-dural puncture headache

ICD-10 code

O29.4

ICD-10 code description

Spinal and epidural anaesthesia-induced headache during pregnancy

Primary outcomes

1

Description

Severity of post dural puncture headache

Timepoint

4-24-48 hour after surgery

Method of measurement

VAS (visual Analog Scale)

Secondary outcomes

1

Description

Time of headache

Timepoint

4-24-48 hour after surgery

Method of measurement

Patients According

Intervention groups

1

Description

Intervention 1:Administration of intravenous Aminophylline 1.5 mg/kg in recovery room after cesarean

Category

Prevention

2

Description

Intervention 2:Administration of intravenous caffeine 30 mg plus 100cc normal saline in recovery room after cesarean.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin
Full name of responsible person
Dr.Heydar Darvish
Street address
In front of Sardar-e Jangle park, end of Shir Mohammadi St, Naziabad
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Islamic Azad University Tehran Medical Science branch
Full name of responsible person
Dr.Hasan Eftekhar Ardebili
Street address
KHaghani St, SHariati St, Tehran
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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 for research Islamic Azad University Tehran Medical Science branch
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