

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the Effect of Intravenous Aminophylline and Ondansetron on Incidence of Post-Dural Puncture Headache in Cesarean Section Surgeries

Protocol summary

Summary

Objective: Comparing the Effect of Intravenous Aminophylline and Ondansetron on Incidence of Post-Dural Puncture Headache in Cesarean Section Surgeries

Study Design: This study is a double blind clinical trial.

Inclusion criteria: women undergoing elective cesarean section under spinal anesthesia ASA class II- I. **Exclusion criteria:** pregnant women; heart disease; chronic liver and kidney failure; migraine headaches and stress; chronic hypertension; gestational hypertension; pre-eclampsia; seizures; psychiatric problems; allergy to ondansetron; aminophylline and theophylline; history of drug addiction; failed to spinal anesthesia or more than once spinal anesthesia attempts. 300 pregnant women were divided into three groups of 100, for each group a 5 cc syringe containing normal saline prepared and labeled A', B' and C' to make the study double-blind. Patients in group (A) (n=100) received 1 mg/kg in 5 cc normal saline Aminophylline after clamping the umbilical cord and A' syringe before performing spinal. Patients in group (B) (n=100) received 0.15 mg/kg in 5 cc normal saline Ondansetron before performing spinal and B' syringe after clamping the umbilical cord. In the control group (C) (n=100) patients received C, C' syringe 5 cc normal saline after clamping the umbilical and before performing spinal as placebo. Primary and secondary outcomes of the study: headache and severity of the headache, incidence of nausea and vomiting every 72, 48, 24 hours in 3 days will be checked and recorded, aminophylline effects on blood pressure and heart rate were also recorded. After clamping the umbilical cord oxytocin is given routinely and after ensuring that blood pressure and heart rate are stable medication is injected, patients were monitored every 15 minutes to the end of the surgery and then in then recovery room, blood pressure and heart rate were also recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110519470N50**

Registration date: **2017-04-04, 1396/01/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-04, 1396/01/15

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-03-10, 1395/12/20

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Intravenous Aminophylline and Ondansetron on Incidence of Post-Dural Puncture Headache in Cesarean Section Surgeries

Public title

Comparing the Effect of Intravenous Aminophylline and Ondansetron on Incidence of Post-Dural Puncture Headache in Cesarean Section Surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: women undergoing elective cesarean section under spinal anesthesia ASA class II- I. Exclusion criteria: pregnant women; heart disease; chronic liver and kidney failure; migraine headaches and stress; chronic hypertension; gestational hypertension; pre-eclampsia; seizures; psychiatric problems; allergy to ondansetron; aminophylline and theophylline; history of drug addiction; failed to spinal anesthesia or more than once spinal anesthesia attempts.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 300

Randomization (investigator's opinion)

N/A

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 Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Postal code**Approval date**

2016-11-02, 1395/08/12

Ethics committee reference number

IR.SUMS.MED.REC.1395.41

Health conditions studied**1****Description of health condition studied**

caesarean section

ICD-10 code

082.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes**1****Description**

headache

Timepoint

every 72, 48, 24 hours in 3 days after surgery

Method of measurement

Numerical rating scale (NRS)

2**Description**

Nausea and vomiting

Timepoint

every 72, 48, 24 hours in 3 days after surgery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups**1****Description**

Patients in group (A) (n=100) received 1 mg/kg in 5 cc normal saline Aminophylline after clamping the umbilical cord and A' syringe before performing spinal.

Category

Treatment - Drugs

2**Description**

Patients in group (B) (n=100) received 0.15 mg/kg in 5 cc normal saline Ondansetron before performing spinal and B' syringe after clamping the umbilical cord.

Category

Treatment - Drugs

3

Description

In the control group(C) (n=100) patients received C, C' syringe 5 cc normal saline after clamping the umbilical and before performing spinal as placebo.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Sanaz Bayani

Street address

Hafez Hospital, Chamran Boulevard

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

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, Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Sanaz Bayani

Position

anesthesiology resident/physician

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Shiraz University of Medical Sciences

Full name of responsible person

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Anesthesiologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

MS in english teaching ,BS in anesthesia/English Consultant

Other areas of specialty/work

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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