Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Effect of intravenous aminophylline on post- spinal anesthesia headache in women under cesarean section

Protocol summary

Study aim
The effect of intravenous aminophylline on post- spinal anesthesia headache in women under cesarean section

Design
Clinical practice with control and intervention group, with parallel groups, simple randomized triple blind

Settings and conduct
In this clinical trial study in Ninth Diabetes Hospital in 1397, each patient was enrolled by an anesthetist after an appointment and then examined for exit criteria. Then, the researcher will prescribe one of the two drugs based on the previously prepared randomized form and the nurse is not known to have any type of drug. For patients who are eligible, the pain questionnaire is filled up before and after 24 hours.

Participants/Inclusion and exclusion criteria
Entry Requirement: Satisfaction to participate in the study Subjected to cesarean section with spinal anesthesia No history of sensitivity to aminophylline or other xanthine derivatives with accurate history from them. Age 45-18 years Lack of history of migraine headaches, coagulation disorders, gestational toxicity, diabetes, seizure, smoking and narcotics, and cardiovascular diseases Conditions for not admitting to study: Performing a retinal anxiety Unwillingness to cooperate in the study General anesthesia Use of xanthine derivatives during the study

Intervention groups
Patients in both intervention and control groups randomly received aminophylline and normal serum saline (0.09%) and normal serum saline (0.09%).

Main outcome variables
Headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180607040003N1**
Registration date: **2018-09-03, 1397/06/12**
Registration timing: **retrospective**

Last update: **2018-09-03, 1397/06/12**
Update count: **0**

Registration date
2018-09-03, 1397/06/12

Registrant information

Name
Hosein Bayesteh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5224 3329

Email address
hosein_bayesteh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2018-08-21, 1397/05/30

Actual recruitment start date
2018-04-21, 1397/02/01

Actual recruitment end date
2018-04-21, 1397/02/01

Trial completion date
empty

Scientific title
Effect of intravenous aminophylline on post- spinal anesthesia headache in women under cesarean section

Public title
Effect of intravenous aminophylline on post- spinal

anesthesia headache in women under cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction to participate in the study Subjected to cesarean section with spinal anesthesia No history of sensitivity to aminophylline or other xanthine derivatives with accurate history from them. Age 45-18 years Lack of history of migraine headaches, coagulation disorders, gestational toxicity, diabetes, seizure, smoking and narcotics, and cardiovascular diseases

Exclusion criteria:

Performing a retinal anxiety Unwillingness to cooperate in the study General anesthesia Use of xanthine derivatives during the study

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

1

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Available sampling from all women candidates for cesarean section with spinal anesthesia referred to Razi Torbat Heydarieh Hospital and Allameh Bhlol Gonabadi Hospital in Gonabad city, after being eligible for inclusion criteria by random allocation method using blocks Reversal, so that the number 1 as an intervention group (the group receiving aminophylline 3 mg based on the ideal body weight and 500 ml normal saline 0.9% venous) and the number 2 as the control group (receiving group 500 C C is considered to be 0.9% venous saline), and 4-block blocks (eg 2121) in the theme

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients in the intervention group, after obtaining informed consent and entering the study, are not aware of which amniotic fluid injectable serum are available. Also, the clinical caregiver of the intervention group is unaware. Only the researcher has prepared the serum and the name of the patient in the intervention group and It will provide control to the clinical care provider for infusion, as well as assessing the outcome of the pain, the clinician will do without the knowledge of the intervention and control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Gonabad University of Medical Sciences

Street address

Asian Roadside Border

City

gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2017-12-17, 1396/09/26

Ethics committee reference number

IR.GMU. REC.1396.62

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

G44

ICD-10 code description

Other headache syndromes

Primary outcomes

1

Description

Headache

Timepoint

24h

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Headache before giving aminophylline in the aminofilin dose group. In this study, 3 cc per kg body weight of the drug are given at the diagnosis of the headache, and after an hour the patient

is examined by the doctor and the healing It is recorded.

Category

Treatment - Drugs

2

Description

Control group: For patients in the control group, only 500 cc normal saline 0.9% intravenous infusion is infused over 2 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Women's Hospital, 9day

Full name of responsible person
hoseyn bayeste

Street address
Razi Ave,Ferdowsi Blv

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Torbat heydarieh

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9516915169

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gonabad 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

Gonabad 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
Gonabad University of Medical Sciences

Full name of responsible person
hoseyn bayeste

Position
Master student of nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Master student of nursing

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available