Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of coffee consumption on post dural puncture headache due to spinal anesthesia in cesarean section

Protocol summary

Summary

The purpose of this study is to examine the effect of Coffee consumption on the prevention of post dural puncture headache due to spinal anesthesia in cesarean section. Inclusion criteria include: age 18-35, perform a cesarean section with spinal anesthesia, insensitivity to coffee and caffeine, anesthesia needle with a similar size (only tried once) , no history of migraine headaches, bleeding disorders, preeclampsia, diabetes, seizures, smoking and drugs. Exclusion criteria include: Bed rest for more than 8 hours after surgery or put the pillow under head in less than 8 hours, drugs or foods containing caffeine and unwillingness to continue cooperation in the study. In this clinical trial, 140 women undergoing cesarean section under spinal anesthesia based on a random allocation method (Balanced Blocking Randomization) will be divided into 2 groups of control and intervention. to patients in the intervention group, 8 hours after surgery, half hour after taking the liquid, 2/31 grams of instant Coffee that in a typical cup contains 118 ml of boiling water twice, each time two cups during one hour Intervals will be given. In the control group Not performed intervention and will received usual care, which will be identical in the two groups. The incidence and severity of headache within 24 hours after surgery in both groups will be checked. The main variable is Coffee consumption that its effect will be evaluated on prevention of headache.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012220750N1**
Registration date: **2015-02-14, 1393/11/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-14, 1393/11/25

Registrant information

Name
Zeynab Banihashemi
Name of organization / entity
Gonabad University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Gonabad University of Medical Sciences

Expected recruitment start date

2015-01-25, 1393/11/05

Expected recruitment end date

2015-03-11, 1393/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of coffee consumption on post dural puncture headache due to spinal anesthesia in cesarean section

Public title

The effect of coffee consumption on post dural puncture headache due to spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria include: desire to participate in the study, at least read and write skills , ages 18-35, perform a cesarean section with spinal anesthesia, no history of previous spinal anesthesia or anesthesia headache after spinal axis, insensitivity to coffee and caffeine, anesthesia by an anesthesiologist with a similar sized needle only one time effort, no history of migraine headaches, bleeding disorders, preeclampsia, diabetes, seizures, smoking, drugs, making class and a state of emergency divided America Society of Anesthesiology physical status. Exclusion criteria: Re spinal anesthesia or general anesthesia for cesarean section, repeated surgery during the study, bed rest for more than 8 hours after surgery or put the pillow under head in less than 8 hours, use of drugs or foods containing caffeine and unwillingness to cooperate in the investigation .

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Gonabad University of Medical Sciences

Street address
Gonabad University of Medical Sciences, Next to the Asian Road

City
Gonabad

Postal code

Approval date
2015-01-07, 1393/10/17

Ethics committee reference number
GMU.REC.1393.94

Health conditions studied

1

Description of health condition studied
post dural puncture headache

ICD-10 code
O89.4

ICD-10 code description
Spinal and epidural anaesthesia-induced headache during the puerperium

Primary outcomes

1

Description
indication post dural puncture headache due to spinal anesthesia

Timepoint
Before and 16 hours after intervention

Method of measurement
Czech Pain Control Lists

Secondary outcomes

1

Description
Headache severity of spinal anesthesia

Timepoint
Before and 16 hours after intervention

Method of measurement
Tools McGill

Intervention groups

1

Description
In the control group Not performed intervention and will received usual care, which will be identical in the two groups.

Category
Prevention

2

Description
intervention group:8 hours after surgery, half hour after taking the liquid ,2/31 grams of instant coffee that in a conventional cup of coffee contains 118 ml of boiling water liquefied in twice, each time two cups (equivalent 300 mg of caffeine) during Intervals of one hour will be given.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Torbat Heydariye Razi Hospital
Full name of responsible person
Zeynab Banihashemi
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Emam Reza Street, Torbat Heydariye
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Gonabad University of Medical Sciences
Full name of responsible person
Mrs Maryam Eshghizadeh
Street address
Gonabad University of Medical Sciences, Next to the Asian Road
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Gonabad
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 of Gonabad 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
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Person responsible for scientific 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