

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 0985157223028

Email address

banihashemi.zeynab@gmu.ac.ir

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 American 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

Street address

Emam Reza Street, Torbat Heydariye

City

Torbat Heydariye

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

City

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

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Zeynab Banihashemi

Position

MSc. student in nursing education

Other areas of specialty/work

Street address

Gonabad University of Medical Sciences, Next to the Asian Road

City

Gonabad

Postal code

Phone

+98 51 5748 3491

Fax

Email

banihashemi.zeynab@gmu.ac.ir;

z.banihashemi66@yahoo.com;

z.banihashemi66@gaile.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Vice chancellor Research Center of Gonabad University of Medical Sciences

Full name of responsible person

Mrs Maryam Eshghizadel

Position

Master of Science in Nursing Education Children orientation

Other areas of specialty/work

Street address

Gonabad University of Medical Sciences, Next to the Asian Road

City

Gonabad

Postal code

Phone

+98 51 5722 3028

Fax

Email

m.eshghizadeh@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Zeynab Banihashemi

Position

MSc. student in nursing education

Other areas of specialty/work

Street address

Gonabad University of Medical Sciences, Next to the Asian Road

City

Gonabad

Postal code

Phone

+98 51 5722 3028

Fax

Email

banihashemi.zeynab@gmu.ac.ir;

z.banihashemi66@yahoo.com;

z.banihashemi66@gaile.com

Web page address

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