Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation prophylactic effect of chamomile oil on headache after spinal anesthesia for elective cesarean section

Protocol summary

Summary

In this research the aim is evaluation of chamomile oil on decrease of post dural puncture headache.148 women in the age range of 19 to 40 without history of migraine or psychiatric problems and negative history of hypersensitivity to chamomile that are going under cesarean section surgery with spinal anesthesia will be divided by their informed consent randomly by blocked randomization method to 2 groups the intervention group and control(placebo) group and will be evaluated in a double blind survey.in the intervention group we use chamomile oil ointment on the forehead of participant 20 minutes before and 2 and 4 hours after spinal anesthesia and in the control group we use placebo that is like the main drug in shape,color and smell but without chamomile oil 20 minutes before and 2 and 4 hours after spinal anesthesia and then we compare the occurrence and severity of headache in this 2 group

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060611341N5**
Registration date: **2017-08-23, 1396/06/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-23, 1396/06/01

Registrant information

Name
Mohammad Hashem Hashempur
Name of organization / entity
Fasa University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 1233 8476
Email address
hashempurm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Fasa University of Medical Sciences

Expected recruitment start date

2017-08-12, 1396/05/21

Expected recruitment end date

2017-09-29, 1396/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation prophylactic effect of chamomile oil on headache after spinal anesthesia for elective cesarean section

Public title

effect of chamomile oil on decrease of headache due to spinal anesthesia in pregnant females

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: pregnant females between 19-40 years that are going under elective cesarean section surgery; informed consent of participants; negative history of migraine or headaches that lasted for more than 2 weeks; negative history of hypersensitivity to chamomile; people who have used analgesics in last 24 hours are not included in the survey; according to American anesthesiologists association standards people physical conditions should be in class 1 or 2; negative

contraindication to intrathecal injection of anesthetic agent; negative history of psychiatric diseases exclusion criteria: The patients who face drop of blood pressure (25% of base systolic blood pressure) while surgery and have to take vasoconstrictors are excluded from survey

Age
From **19 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **148**

Randomization (investigator's opinion)
Randomized

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 Fasa University of Medical Sciences

Street address
Ebn-e-sina square

City
Fasa

Postal code

Approval date
2017-07-25, 1396/05/03

Ethics committee reference number
IR.FUMS.REC.1396.214

Health conditions studied

1

Description of health condition studied
headache after dura mater puncture

ICD-10 code
O29.4

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

Primary outcomes

1

Description
occurence rate of headache due to dura mater puncture and its severity

Timepoint
0 ,6 ,12 and 24 hours after surgery

Method of measurement
visual analoge scale vas ruler

Secondary outcomes

1

Description
occurence rate of probable side effects

Timepoint
0,6,12 and 24 hours after surgery and use of chamomilla oil

Method of measurement
occurrence of probable side effects

2

Description
nausea and vomiting

Timepoint
0,6,12 and 24 hours after surgery and use of chamomilla oil

Method of measurement
occurrence of nausea and vomiting

Intervention groups

1

Description
in intervention group participants use chamomile oil ointment on their forehead 20 minutes before and 2 and 4 hours after lumbar puncture

Category
Treatment - Drugs

2

Description
in control group participants use placebo 20 minutes before and 2 and 4 hours after lumbar puncture on their forhead

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Fasa Valiasr hospital

Full name of responsible person

Alireza Mohebbinejad

Street address

City

Fasa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa university of medical sciences

Full name of responsible person

Dr Mojtaba Farjam

Street address

Ebn-e-Sina square Fasa University of Medical Sciences

City

Fasa

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Fasa 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

Fasa University of Medical Sciences

Full name of responsible person

Alireza Mohebbinejad

Position

medicine student

Other areas of specialty/work

Street address

Fasa University of Medical Sciences

City

Fasa

Postal code

Phone

+98 71 5335 0994

Fax

Email

mohebbi71@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hashem Hashempur

Position

Assistant Professor of traditional Iranian medicine

Other areas of specialty/work

Street address

Fasa University of Medical Sciences

City

Fasa

Postal code

Phone

+98 71 5335 0994

Fax

Email

hashempur@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Alireza Mohebbinejad

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

mohebbi71@yahoo.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