

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 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

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###### 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**

occurrence 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**

occurrence 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 forehead

##### **Category**

Placebo

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Fasa Valiasr hospital

###### **Full name of responsible person**

Alireza Mohebbinejad  
**Street address**  
**City**  
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## 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  
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## Person responsible for scientific inquiries

### Contact

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Assistant Professor of traditional Iranian medicine  
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## Person responsible for updating data

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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*