

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparing the effect of Cumin and Supermint (Peppermint Oil) and Milk of Magnesia on Gastrointestinal Complications after Caesarean Section

#### Protocol summary

##### Summary

Cesarean section, one of the most common surgeries, has complications such as flatulence, nausea, belching and flatus. we used cumin and supermint in the current study. The study population comprised all pregnant women undergoing cesarean section with the following inclusion criteria: no history of gastrointestinal diseases, no adhesion observed during surgery....). The sample size was 83 people. Interventions began the day after the surgery simultaneous with drinking tea and before having a meal for 3 times with a 20-min interval. Each group (1, 2 and 3) that were randomly selected received 40 drops of cumin and supermint in 30 ml of water and 30 ml of syrup respectively. Twenty minutes and 120 minutes after the first intervention, the questionnaire was completed. In fact, the third group (milk of magnesia) received the routine medication of the hospital and were considered the control group. For each medicine group, the intended medicine was poured into graduated containers by an assistant and the researcher was blinded to the contents and gave the patients the form of double-blind trial. All participants in the study were matched in terms of cesarean section period and normal BMI (26-19). ). After taking the first dose of the medicine, at the end of 20 min the questionnaire was filled out and questions about all variables (nausea, vomiting, etc.) were asked of the patients step by step and were marked on the questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014062918280N1**

Registration date: **2014-08-15, 1393/05/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-08-15, 1393/05/24

##### Registrant information

###### Name

Maryam Tofighi Niaki

###### Name of organization / entity

Islamic Azad University Sari Brabch

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3303 3857

###### Email address

maryamtofighi@iausari.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Chancellor for research Of Islamic Azad University Sari Branch

##### Expected recruitment start date

2012-08-21, 1391/05/31

##### Expected recruitment end date

2014-01-20, 1392/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of Cumin and Supermint (Peppermint Oil) and Milk of Magnesia on Gastrointestinal Complications after Caesarean Section

##### Public title

The effect of drugs on gastrointestinal complications after caesarean

##### Purpose

Supportive

### **Inclusion/Exclusion criteria**

Inclusion Criteria: uneventful transects ; Singleton infant;Term pregnancy(38-42); No blood transfusion;Second repeat cesarean;normal BMI(19-26); With general anesthesia. Exclusion Criteria:History of surgical adhesions;fever;Gastrointestinal disorders (colitis, Cron,IBS);Gastritis drugs;Spinal anesthesia

### **Age**

From **22 years** old to **32 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **83**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double 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 The Islamic Azad University Sari Branch

##### **Street address**

Phyrozkandeh ,Darya Street, Sari

##### **City**

Sari

##### **Postal code**

4816119318

##### **Approval date**

2012-05-07, 1391/02/18

##### **Ethics committee reference number**

03

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Pregnancy, childbirth and the puerperium

#### **ICD-10 code**

O85,O92

### **ICD-10 code description**

Complications predominantly related to the puerperium

## **Primary outcomes**

### 1

#### **Description**

Defecation

#### **Timepoint**

every 20 min and 120 min after the end of the firrst intervention

#### **Method of measurement**

Questionnaire to yes/No

### 2

#### **Description**

Bloating

#### **Timepoint**

every 20 min and 120 min after the end of the firrst intervention

#### **Method of measurement**

Questionnaire to yes/No

## **Secondary outcomes**

### 1

#### **Description**

Nausea

#### **Timepoint**

every 20 min and 120 min after the end of the first intervention

#### **Method of measurement**

Questionnaire to yes/no

### 2

#### **Description**

Heart burn

#### **Timepoint**

every 20 min and 120 min after the end of the first intervention

#### **Method of measurement**

Questionnaire to yes/no

### 3

#### **Description**

Belching

#### **Timepoint**

every 20 min and 120 min after the end of the first intervention

#### **Method of measurement**

Questionnaire to yes/no

### 4

#### **Description**

Flatus

#### **Timepoint**

every 20 min and 120 min after the end of the first intervention

**Method of measurement**

Questionnaire to yes/no

**5**

**Description**

vomiting

**Timepoint**

every 20 min and 120 min after the end of the first intervention

**Method of measurement**

Questionnaire to yes/no

**Intervention groups**

**1**

**Description**

The intervention group: cumin: 40 drops in 30 cc municipal tap water 3 times with 20-minute intervals

**Category**

Treatment - Drugs

**2**

**Description**

The intervention group: peppermint essential oil : 40 drops in 30 cc municipal tap water 3 times with 20-minute intervals

**Category**

Treatment - Drugs

**3**

**Description**

The Control group: milk of magnesia: 30 cc , 3 times with 20-minute intervals

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Tahereh Asadi

**Street address**

**City**

Sari

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

The Islamic Azad University Sari Branch

**Full name of responsible person**

Hamed Samadi

**Street address**

Phyrozkandeh ,Darya Street

**City**

Sari

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

The Islamic Azad University Sari Branch

**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**

The Islamic Azad University Sari Branch

**Full name of responsible person**

Maryam Tofighi Niaki

**Position**

Msc/Faculty Member

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Islamic Azad University Sari Branch  
**Full name of responsible person**  
Maryam Tofighi Niaki  
**Position**  
Msc/Faculty Member  
**Other areas of specialty/work**  
**Street address**  
Phyrozkandeh, Darya Street  
**City**  
Sari  
**Postal code**

## 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*