# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## The effect of selective production base on Carum carvi on early return of bowel motility after caesarean section

### Protocol summary

**Summary**

This study is a randomized controlled trial study that will be done on 90 women from the 22 December 2013 to 21 March 2014 at the Emam khomeini Hospital in Sari will be delivered by cesarean section .Intervention Group are consisted of 45 cases that drink 20 ml of the syrup that has 2 mg of Carum Carvi in two half-hour interval, 6 hours after surgery. Control group are consisted of 45 cases that drink 20 ml of the placebo in two half-hour interval, 6 hours after surgery. These groups will be observed under the routine care after cesarean. Thus, their feeding will be started after bowel sounds auscultation and flatus, with clear liquid. Soft and normal diet will be started after defecation. We have to check the sounds of bowel every 30 minutes until it will be heard, the time to the first passage of flatus and defecation and bowel motility and Coming down from the bed and the time until the discharge from the hospital will be completed by patient in a special check list. Measurable results are: the time of first bowel sounds auscultation, first flatus, first bowel motility and hospital discharge. Data using SPSS-17 software and descriptive and inferential statistical tests (chi-square, T test, ANOVA and paired comparisons) will be analyzed. In this study, P <0.05 was considered as statistically significant.

### General information

**Acronym**

The effect of Carum carvi

**IRCT registration information**

IRCT registration number: **IRCT2013082614486N1**
Registration date: **2013-12-28, 1392/10/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2013-12-28, 1392/10/07

**Registrant information**

**Name**

Seyed Sedighe Yoosefi

**Name of organization / entity**

Tehran University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 15 1325 4066

**Email address**

s-yousefi@sina.tums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

This study is funded by Tehran University of Medical Sciences.

**Expected recruitment start date**

2013-12-22, 1392/10/01

**Expected recruitment end date**

2014-03-21, 1393/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of selective production base on Carum carvi on early return of bowel motility after caesarean section

**Public title**

The effect of selective production base on Carum carvi on early return of bowel motility after caesarean section

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: fasting for at least 8 hours before

surgery; received a maximum of 4 doses of intravenous antibiotics; having a gestational age of 42-38 weeks; having good vital signs; no unusual complications of surgery; absence of fever before operation; lack of medical disorders and obstetric patients addicted to cigarettes and illegal drugs are not. Exclusion criteria: the patient withdrew from the study, those at risk for ileus and aspiration ( background radiation , anastomotic stricture , peptic ulcer, esophagitis, intestinal obstruction ), a lot of individuals taking sedatives, obstetric complications such as fatty liver of pregnancy, preeclampsia, diabetes, placental abruption, chorioamnionitis, post-operative complications ( atonic uterus, antibiotic therapy, more than four doses ), intraoperative complications ( severe adhesion, blood transfusion, injury to bowel and bladder ), personal discharge, during over 90 minutes, the use of magnesium sulfate for the possibility of nausea, infection, hypothyroidism, hyperparathyroidism, neuromuscular disease, excessive intestinal manipulation is obvious.

**Age**
From **20 years** old to **40 years** old

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **90**

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

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**
Questionnaire by a person who is unaware of the grouping of the subjects will be completed.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee, Faculty of Traditional Medicine, Tehran University of Medical Sciences

**Street address**
Islamic Medicinal Research Institute, Pirnia Ave., Lalehzar St., Tehran, Iran

**City**
Tehran

**Postal code**

**Approval date**
2013-05-27, 1392/03/06

**Ethics committee reference number**
115/26/پ/ط/م

## Health conditions studied

### 1

**Description of health condition studied**
Postoperative intestinal obstruction

**ICD-10 code**
K91.3

**ICD-10 code description**
Postoperative intestinal obstruction

## Primary outcomes

### 1

**Description**
Bowel sound

**Timepoint**
Each half-hour intervals , one hour after the intervention until the first sound will be heard

**Method of measurement**
Bowel sound auscultation by Stethoscope

### 2

**Description**
Flatus

**Timepoint**
First flatus

**Method of measurement**
Check list

### 3

**Description**
Defecation

**Timepoint**
The first defecation after caesarean

**Method of measurement**
Check list

### 4

**Description**
The time of discharge

**Timepoint**
At discharge

**Method of measurement**
Check list or file

## Secondary outcomes

### 1

**Description**
Bloat

**Timepoint**
Befor and after intervention
**Method of measurement**
Questionnaire

## Intervention groups

### 1

**Description**
This study will be done on 90 women from the 22 December 2013 to 21 March 2014 at the Emam khomeini Hospital in Sari will be delivered by cesarean section .Intervention Group are consisted of 45 cases that drink 20 ml of the syrup that has 2 mg of Carum Carvi in two half-hour interval, 6 hours after surgery. This group will be observed under the routine care after cesarean. Thus, their feeding will be started after bowel sounds auscultation and flatus, with clear liquid. Soft and normal diet will be started after defecation. We have to check the sounds of bowel every 30 minutes until it will be heard, the time to the first passage of flatus and defecation and bowel motility and Coming down from the bed and the time until the discharge from the hospital will be completed by patient in a special check list.
**Category**
Treatment - Drugs

### 2

**Description**
Control group are consisted of 45 cases that drink 20 ml of the placebo in two half-hour interval, 6 hours after surgery. This group will be observed under the routine care after cesarean. Thus, their feeding will be started after bowel sounds auscultation and flatus, with clear liquid. Soft and normal diet will be started after defecation. We have to check the sounds of bowel every 30 minutes until it will be heard, the time to the first passage of flatus and defecation and bowel motility and Coming down from the bed and the time until the discharge from the hospital will be completed by patient in a special check list.
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Sari Emam Khomeini hospital
**Full name of responsible person**
Zoleikha Atarod Gynecologist and Head of Department
**Street address**
Amir Mazandarani Av.
**City**
Sri

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Dr. Minaei; Vice chancellor for research Traditional Medicine Faculty of Tehran University of Medica
**Full name of responsible person**
Dr. Minaei
**Street address**
Behesht Street, Vahdat eslami Ave.
**City**
Tehran
**Grant name**
فرناز سهرابوند
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Dr. Minaei; Vice chancellor for research Traditional Medicine Faculty of Tehran University of Medica
**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**
Traditional Medicine Faculty, Tehran University of Medical Sciences
**Full name of responsible person**
Seyde Sedighe Yosefi
**Position**
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**Other areas of specialty/work**
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## Person responsible for scientific

## inquiries

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Associated professor

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## Person responsible for updating data

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dr_ssyosefi@yahoo.com; s-yousefi@sina.tums.ac.ir

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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*