

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The efficacy of topical Chamomile oil, an Iranian traditional medicine, compared with placebo on recovery of bowel function following cesarean: a randomized controlled trial

Protocol summary

Summary

The aim of this study is evaluation of the effect of Topical chamomile on reduction of ileus after cesarean section. The population of this study is women candidates of cesarean section in gynecological hospital of Mirza Khogek Khan in Tehran and in Mobini hospital of Sabzevar. In this study 150 samples will be enrolled after approval of ethics committee and informed consent form. After surgery samples were randomly allocated to the intervention group (Topical application of chamomile oil) and placebo group (receiving sesame oil) and control group (routine treatment). A questionnaire is completed on demographic characteristics and objectives of study for each of the participants. In the intervention group 15 drops of chamomile oil will be applied on abdominal region immediately after consciousness every half hour in the first hour. The second to the fourth hour, every hour, then every 8 hours until discharges time. With same method, placebo group received sesame oil. Routine care is for all three groups. Data collection is included interviews, questionnaires and examination. The Time of bowel movement, flatus and defecation, feeling of hunger is noted. The data collected are analyzed by statistical analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082818951N1**
Registration date: **2014-11-12, 1393/08/21**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-11-12, 1393/08/21

Registrant information

Name

Fereshteh Ghorat

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5558 0386

Email address

f-ghorat@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2015-01-20, 1393/10/30

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of topical Chamomile oil, an Iranian traditional medicine, compared with placebo on recovery of bowel function following cesarean: a randomized controlled trial

Public title

The efficacy of Chamomile on recovery of bowel function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women undergoing cesarean

section; a minimum age of 18 years and maximum 35 years; gestational age 42-38 weeks; .starvation at least 8 hours before surgery; Stable vital signs; consent for participation in the study. Exclusion criteria: epidural anesthesia; a vertical incision in the abdomen and uterus to surgery; history of previous abdominal surgery other than cesarean; history of chronic inflammatory bowel disease and gastrointestinal disease; intraoperative complications (severe adhesions and manipulation of the bowel; blood transfusions, damage to the bowel and bladder); postoperative complications (atonic uterus, infection Academy); blood transfusions during or after surgery; length of surgery more than 90 minutes; the skin lesion at the site of the study; medical and obstetric disorders (thyroid disease, severe digestive disorders, diabetes, pre eclampsia); received narcotic analgesic more than one dose (1mg / kg); smoking and addiction; refuse of the patient from the study

Age

From **16 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Enghelab street, Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2015-01-28, 1393/11/08

Ethics committee reference number

134808

Health conditions studied

1

Description of health condition studied

Ileus

ICD-10 code

K56.0

ICD-10 code description

Paralytic ileus

Primary outcomes

1

Description

Time to first flatus after surgery

Timepoint

Every three hour

Method of measurement

Reported by the patient

Secondary outcomes

1

Description

Bowel sound

Timepoint

Every 3 hour

Method of measurement

Stethoscope

2

Description

Time of defecation

Timepoint

Every 3 hour

Method of measurement

Reported by the patient

3

Description

Time to start diet

Timepoint

Every 3 hour

Method of measurement

The patient's medical records

Intervention groups

1

Description

In the intervention group 15 drops of chamomile oil will be applied on abdominal region immediately after consciousness every half hour in the first hour. The second to the fourth hour, every hour, then every 8 hour until discharge time.

Category

Treatment - Drugs

2

Description

In the placebo group 15 drops of Sesame Oil will be applied on abdominal region immediately after consciousness every half hour in the first hour. The second to the fourth hour, every hour, then every 8 hours until discharge time.

Category

Treatment - Drugs

3

Description

Control patients receive routine care

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecological Hospital of Mirza Khogek Khan

Full name of responsible person

Fereshteh Ghorat

Street address

Valiasr Square, Karimkhan Street, Vila Street

City

Tehran

2

Recruitment center

Name of recruitment center

Mobini Hospital

Full name of responsible person

Fereshteh Ghorat

Street address

Kashefi Street

City

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mis Roja Rahimi

Street address

Tehran University of Medical Sciences, School of Traditional Medicine

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

School of Traditional Medicine. Tehran University of Medical Sciences

Full name of responsible person

Fereshteh Ghorat

Position

PHD Student in Traditional Medicine

Other areas of specialty/work

Street address

School of Traditional Medicine. Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 51 4464 1144

Fax

Email

f-ghorat@razi.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Traditional Medicine. Tehran University of Medical Sciences

Full name of responsible person

Ebrahim Khadem Azghandi

Position

Assistant Professor in Traditional Medicine

Other areas of specialty/work

Street address

School of Traditional Medicine. Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 51 4464 1144

Fax

Email

dr.ebrahim.khadem@yahoo.com

Web page address

+98 51 4464 1144

Fax**Email**

f-ghorat@razi.tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

School of Traditional Medicine Tehran University of
Medical Sciences

Full name of responsible person

Fereshteh Ghorat

Position

PHD Student in Traditional Medicine

Other areas of specialty/work**Street address**

School of Traditional Medicine, Tehran University of
Medical Sciences

City

Tehran

Postal code**Phone****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