Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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 defication

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
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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