Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effectiveness of administering oral capsules containing hydroalcoholic extract of Rosa damascena compared to routine care on bowel function after cesarean section in women who have undergone cesarean section.

Protocol summary

Study aim
The effect of oral Rosa damacene capsules on intestinal function after cesarean section

Design
A controlled clinical trial with parallel groups, single-blind, randomized, on 88 patients, using block design for randomization.

Settings and conduct
Sampling is available (easy); on all women who underwent cesarean section and were hospitalized in the gynecological ward of Imam Sajjad Hospital; single-blind randomized clinical trial; blind statistical analyzer.

Participants/Inclusion and exclusion criteria
Age between 18-45 years; Candidate for elective cesarean section with local spinal anesthesia; Fasting for at least 8 hours; Cooperation and written consent to participate in the study; Gestational age 38-42 weeks; Good vital signs in mother and baby ; Use of anticoagulants and analgesics; Unusual complications during surgery; Medical or gynecological disorders; Diarrhea-vomiting or bloating in the past 48 hours; Patients with postoperative complications such as uterine atony; Patients with intraoperative complications; Surgery lasting more than 90 minutes; Those receiving heavy doses of intraoperative sedation; Cesarean section more than four

Intervention groups
Participants will be divided into two intervention and control groups, and the intervention group will receive capsules containing 500 mg of hydroalcoholic extract of rose petals at 4 hours after the operation, and then this dose will be repeated three times at one-hour intervals. The control group will be given 30 cc of magnesium hydroxide syrup starting eight hours after the cesarean section, and then it will continue every eight hours until the onset of signs of bowel function.

Main outcome variables
Time interval between first bowel movement, first gas and first bowel sound since cesarean section,Length of hospital stay after cesarean section, Mother's age, number of cesarean deliveries,number of pregnancies

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250629066297N1**
Registration date: **2025-08-03, 1404/05/12**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-03, 1404/05/12**
Update count: **0**

Registration date
2025-08-03, 1404/05/12

Registrant information
Name
Nasrin Tavakoli
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3339 1943
Email address
tavakoli.nasrin.2015@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-06-29, 1404/04/08

Expected recruitment end date
2026-01-27, 1404/11/07
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of administering oral capsules containing hydroalcoholic extract of Rosa damascena compared to routine care on bowel function after cesarean section in women who have undergone cesarean section.

Public title
Investigating the effect of oral capsules containing hydroalcoholic extract of Rosa damascena petals on bowel function after cesarean section
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-45 years Candidate for elective cesarean section with local spinal anesthesia Fasting for at least 8 hours before cesarean section surgery Cooperation and consent to participate in the study Signing a written informed consent form Gestational age 38 to 42 weeks Good vital signs in mother and baby (maternal vital signs within normal limits and infant signs within normal limits for the infant)
Exclusion criteria:
Use of anticoagulant drugs Use of painkillers and sedatives Unusual complications during surgery Having medical or gynecological disorders, such as hypothyroidism, diabetes, or neuromuscular disorders History of irritable bowel syndrome and idiopathic constipation Diarrhea, vomiting, or bloating in the past 48 hours Patients with postoperative complications such as uterine atony Patients with intraoperative complications (severe adhesions, excessive bowel manipulation, excessive blood loss or transfusion, and damage to the bowel or bladder) Patients whose surgery lasts more than 90 minutes Those who receive heavy doses of sedation during surgery Cesarean section above four
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be used to allocate subjects to study groups. The advantages of blocked randomization are that it ensures a balance of patient numbers in each group. The groups are defined as codes A and B. Each eligible person who applies will be assigned to one of the groups. To avoid the risk of predictably assigning people to different groups, blocks of different sizes (2,4,6,8) will be created.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, to blind the study, only the statistical analyst is blind to the groups. And the participants and the researcher are not blind to the intervention performed due to the difference in the form of medication and care. Only the statistical analyst is blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Yasuj University of Medical Sciences
Street address
Shahid Motahari Blvd., Yasuj University of Medical Sciences Headquarters
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Approval date
2025-06-28, 1404/04/07
Ethics committee reference number
IR.YUMS.REC.1404.077

Health conditions studied

1

Description of health condition studied
complications of the puerperium
ICD-10 code
O90.8
ICD-10 code description
Other complications of the puerperium, not elsewhere classified

2

Description of health condition studied

functional intestinal disorders

ICD-10 code

K59.8

ICD-10 code description

Other specified functional intestinal disorders

Primary outcomes

1

Description

Time interval from first bowel movement to cesarean section

Timepoint

From four hours after the cesarean section, every hour until 24 hours after the cesarean section

Method of measurement

All patients were asked to record the time of their first bowel movement and report it to the researcher or record it on the postoperative evaluation form.

2

Description

The interval between the first gas release and the time of cesarean section

Timepoint

From four hours after the cesarean section, every hour until 24 hours after the cesarean section

Method of measurement

All patients were asked to record the time of the first gas release and inform the researcher.

3

Description

Time interval from the time of first bowel sound to cesarean section

Timepoint

Information regarding the first hour of bowel sound auscultation is reviewed and recorded by the researcher every hour until the sound is auscultated.

Method of measurement

Information regarding the first hour of bowel sound auscultation is reviewed and recorded by the researcher every hour until the sound is auscultated.

Secondary outcomes

1

Description

Length of hospital stay

Timepoint

Length of hospital stay after cesarean section in hours

Method of measurement

From the time of cesarean section to discharge in hours

Intervention groups

1

Description

Intervention group: Receive capsules containing hydroalcoholic extract of rose petals. Oral capsule containing rose extract: First, rose petals are prepared and approved by a herbalist.The petals are separated and then dried and ground, and then 200 grams of powder is ground. The rose petals are mixed with 76% ethanol, and after 72 hours, they are mixed and strained into a container where they are poured, and in the next step, they are dried by a rotary machine at a temperature of 46 degrees Celsius until completely dry.It was then placed in the freezer and used in the required dosage when used in capsule making. The dose of ground rosehip extract is selected based on the conversion of animal dose to human dose. According to the research of Abbaszadeh et al. (2010), a dose of 180-190 mg per rosehip flower causes laxative production, and this dose is prepared according to the research of Nayyari et al. (2016).To check for sensitivity, the first capsule is tested on the research group and allergy symptoms are checked. The mother is also asked to inform the researcher if any allergy symptoms appear after the first use.In case of allergy, the participant will be excluded from the study and the drug will not be used and a specialist will be informed to treat the allergy. After cesarean section, no patient will be given oral or rectal bowel stimulants. In both intervention and control groups, all women were cared for with the same postoperative protocols.Oral intake of clear liquids and soft foods begins eight hours after the operation. After delivery, necessary training on how to care for the stitches, personal hygiene, nutrition, physical and sexual activity, and the frequency and method of taking the capsules, time and place of follow-up visits is provided equally to both groups by the researcher through face-to-face training.Patients are then treated with capsules starting 4 hours after surgery. At 4 hours after surgery, a capsule containing 500 mg of extract is administered, and then this dose is repeated three times at one-hour intervals. Participants are asked to record symptoms, complaints, and side effects (heartburn, diarrhea, abdominal cramps, etc.) as well as the time of drug administration on a report sheet and to inform the researcher if any problems occur.The researcher provides participants with a telephone number so that they can contact the researcher in case of problems or questions. All patients were asked to record the time of the first gas and the time of the first bowel movement and to inform the researcher. Information related to the first hour of bowel sound auscultation is reviewed and recorded by the researcher every hour until the time of sound auscultation.

Category

Diagnosis

2

Description

Control group: Control group: The control group will be provided with all routine care similar to the intervention group, and starting eight hours after the cesarean

section, 30 cc of magnesium hydroxide syrup will be given according to the hospital routine, starting with the start of supplementary feeding, and then it will continue every eight hours until symptoms of intestinal function appear.All patients were asked to record the time of the first gas and the time of the first bowel movement and to inform the researcher. Information regarding the first hour of bowel sound auscultation was reviewed and recorded by the researcher every hour until the time of sound auscultation.

Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Sajjad Hospital
Full name of responsible person
Dr. Younes Hatamipour
Street address
next to Azadi Hotel,Kohkiluyeh and Boyer Ahmad
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
75919
Phone
+98 74 3322 0165
Email
emamsajad@yums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Dr. Sirous Salehnasb
Street address
Shahid Zarei Educational Campus,Beach Park towards Imam Sajjad (AS) Hospital,Yasuj
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
۷۵۹۱۷۴۱۴۱۷
Phone
+98 74 3323 5153
Email
Medical@yums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Nasrin Tavakoli
Position
The second executive of the plan
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
No. 147 Baharestan Alley, Ahangaran Street, Kaveh Boulevard
City
Isfahan
Province
Isfehan
Postal code
8138686946
Phone
+98 31 3339 1943
Email
Tavakoli.nasrin.2015@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Fatemeh Goodarzi
Position
assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Shahid Zarei Educational Campus,Beach Park towards Imam Sajjad (AS) Hospital,Yasuj
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591741417
Phone
+98 74 3323 5153
Email
godarzi56@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Nasrin Tavakoli
Position
The second executor of the plan
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
No. 147 Baharestan Alley, Ahangaran Street, Kaveh Boulevard
City
Isfahan
Province
Isfehan
Postal code
813868946
Phone
+98 31 3339 1943
Email
Tavakoli.nasrin.2015@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Total data from informed consent forms in research designs and Total data from demographic information forms and Total data from the post-cesarean section symptom register and Total data entered into SPSS software
When the data will become available and for how long
The data will be kept by the corresponding author for at least five years.
To whom data/document is available
Competent individuals, such as editors of journals publishing study data reports
Under which criteria data/document could be used
Reasonable request from competent persons while maintaining confidentiality and secrecy.
From where data/document is obtainable
Dr. Fatemeh Godarzi Work address, Yasuj, Beach Park, towards Imam Sajjad Hospital (AS), Shahid Zarei Educational Campus, Faculty of Medicine Email: godarzi56@yahoo.com
What processes are involved for a request to access data/document
Send a message to godarzi56@yahoo.com and request the type of data. After reviewing the request, if it does not conflict with the principle of confidentiality and secrecy, the data will be sent to them as a PDF file within a maximum of one week, and if requested, the analysis data file will be sent to them as the results of the analysis in SPSS.
Comments