

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of rosa damascena oil capsule in reducing ileus after colorectal surgery

Protocol summary

Study aim

The effect of rosa damascena oil capsule in reducing ileus after colorectal surgery

Design

The study will be double blind and clinical trial. 84 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3

Settings and conduct

Patients candidate for colorectal surgery in valiasr Hospital in Arak are divided into 2 groups by simple randomization with blocks. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 80 years, do not enter patients with coagulation problems who are unable to discontinue their medication, failure to enter patients receiving regular glucocorticoids and nonsteroidal anti-inflammatory drugs more than three days a week for the past 28 days, do not take aspirin daily at a dose of more than 150 mg, no acute peptic ulcer or its complications, failure to receive antibiotic treatment to eradicate Helicobacter pylori in the last 28 days, do not smoke or drink alcohol, lack of sensitivity to sesame and its products
Exclusion criteria: Incidence of complications compared to rosemary during treatment, the patient's unwillingness to continue treatment

Intervention groups

Intervention group: Two soft capsules of Golmohammadi (Barij Esans .Co) are taken orally three times a day for 3 days with routine care. Control group: receive routine care and placebo in the same way and number of intervention drugs.

Main outcome variables

Incidence of ileus, time of first gas excretion, duration of hospital stay, abdominal distension, abdominal circumference

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N173**

Registration date: **2022-04-09, 1401/01/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-09, 1401/01/20**

Update count: **0**

Registration date

2022-04-09, 1401/01/20

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

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f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date

2022-09-11, 1401/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of rosa damascena oil capsule in reducing ileus after colorectal surgery

Public title

The effect of rosa damascena oil capsule in reducing ileus after colorectal surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 80 years Do not enter patients with coagulation problems who are unable to discontinue their medication Failure to enter patients receiving regular glucocorticoids and nonsteroidal anti-inflammatory drugs more than three days a week for the past 28 days Do not take aspirin daily at a dose of more than 150 mg No acute peptic ulcer or its complications Failure to receive antibiotic treatment to eradicate Helicobacter pylori in the last 28 days Do not smoke or drink alcohol Lack of sensitivity to sesame and its products

Exclusion criteria:

The patient's unwillingness to continue treatment

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)

Double blinded

Blinding description

It is a double-blind study. Analysts, evaluators, and participants are unaware of the grouping.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2022-02-13, 1400/11/24

Ethics committee reference number

IR.ARAKMU.REC.1400.323

Health conditions studied

1

Description of health condition studied

Colorectal surgery

ICD-10 code

K56.49

ICD-10 code description

Other impaction of intestine

Primary outcomes

1

Description

Incidence of ileus

Timepoint

Before and after intervention

Method of measurement

Number

2

Description

Time of first gas excretion

Timepoint

After of surgery

Method of measurement

Minute

3

Description

length of hospital stay

Timepoint

After intervention

Method of measurement

day

4

Description

Abdominal distension

Timepoint

Before and after intervention

Method of measurement

Observation

5

Description

Abdominal circumference

Timepoint

Before and after intervention

Method of measurement

Centimeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Two soft capsules of Golmohammadi (Barij Esans .Co) are taken orally three times a day for 3 days with routine care.

Category

Treatment - Drugs

2

Description

Control group: receive routine care and placebo in the same way and number of intervention drugs.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Valiasr Hospital

Full name of responsible person

Dr Reza Shojaee

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Valiasr square, Valiasr hospital

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available