

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of Cuminum Cyminum on the return of intestinal peristaltic movements after abdominal surgeries in patients who hospitalized in the surgery ward of Ali Ibn Abi Taleb Hospital of Rafsanjan, 2021

Protocol summary

Study aim

Determination the effect of Cuminum Cyminum on the return of intestinal peristaltic movements after abdominal surgeries

Design

Randomized, parallel group trial with blinded drug and outcome assessment

Settings and conduct

In this randomized clinical trial, the study population are candidates for abdominal surgery who will admitted to the Ali Ibn Abitaleb Hospital of Rafsanjan. Participants will select by convenience sampling method based on inclusion criteria of the study. Random allocation of the participants will carry out using the minimization method based on type of surgery and sex variables. Participants will be divided into two groups of intervention (will receive 250 mg capsule of Cuminum Cyminum extract 4 hours after surgery and one hour after the first dose of this drug) and control (will receive placebo exactly like the intervention group). Demographic questionnaire and the check list for recording of bowel movement are data collection tool which will completed each 2 hours after the surgery until to 24 hours in both groups.

Participants/Inclusion and exclusion criteria

Age between 18-60 years, candidate for abdominal surgery, general anesthesia, inform consent for participate in the study are inclusion criteria. Use of Cuminum Cyminum permanently, pregnancy and lactation, addiction, use of alcohol, history of liver, kidney, heart and thyroid disorders, use of anticoagulant drugs, use of psychiatric drugs and gastric perforation are exclusion criteria.

Intervention groups

Intervention group: In this group, patients receive a 250 mg capsule of Cuminum Cyminum extract 4 hours after surgery and one hour after the first dose of this drug.

Control group: In this group, patients will receive placebo (a 250 mg capsule of starch) exactly like the intervention group.

Main outcome variables

First gas passing First defecation Abdominal bloating Abdominal pain Nausea Vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150713023190N10**

Registration date: **2021-10-24, 1400/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-24, 1400/08/02**

Update count: **0**

Registration date

2021-10-24, 1400/08/02

Registrant information

Name

Tabandeh Sadeghi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

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t.sadeghi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Cuminum Cyminum on the return of intestinal peristaltic movements after abdominal surgeries in patients who hospitalized in the surgery ward of Ali Ibn Abi Taleb Hospital of Rafsanjan, 2021

Public title

Effect of Cuminum Cyminum on the return of intestinal peristaltic movements after abdominal surgeries

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18-60 years Candidate for abdominal surgery General anesthesia Inform consent for participate in the study

Exclusion criteria:

Use of Cuminum Cyminum permanently pregnancy and lactation Addiction Use of alcohol History of liver, kidney, heart and thyroid disorders Use of anticoagulant drugs Use of psychiatric drugs Gastric perforation

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample sizeTarget sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

Stratified randomization by minimization method: in this method, initially, the patients will categorize based on key variables, such as type of surgery and gender. Afterwards, from the patients who will meet the inclusion criteria, the first participant will place in the intervention or control group by coin flip, and other participants will allocate to the study group with lower total of variables.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient will not know that he/she is in the intervention group or control. The capsules will be prepared by pharmacist and the researcher will not be

aware of the capsules. The analyzer will not know the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2021-10-02, 1400/07/10

Ethics committee reference number

IR.RUMS.REC.1400.135

Health conditions studied**1****Description of health condition studied**

Return of intestinal peristaltic movements

ICD-10 code

R19.11

ICD-10 code description

Absent bowel sounds

Primary outcomes**1****Description**

First gas passing

Timepoint

After the intervention

Method of measurement

Checklist (patient' response will be recorded in the checklist)

2**Description**

First defecation

Timepoint

After the intervention

Method of measurement

Checklist

3

Description

Abdominal bloating

Timepoint

2 hour after the intervention until 24 hours

Method of measurement

Checklist

4

Description

Abdominal pain

Timepoint

2 hour after the intervention until 24 hours

Method of measurement

Checklist

5

Description

Nausea

Timepoint

2 hour after the intervention until 24 hours

Method of measurement

Checklist

6

Description

Vomiting

Timepoint

2 hour after the intervention until 24 hours

Method of measurement

Checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients receive a 250 mg capsule of Cuminum Cyminum extract 4 hours after surgery and one hour after the first dose of this drug.

Category

Treatment - Other

2

Description

Control group: In this group, patients will receive placebo (a 250 mg capsule of starch) exactly like the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abitaleb Hospital

Full name of responsible person

Ali Mousavi

Street address

Mofateh Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan 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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Amin Esmaeili Abdar

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Position

Associate Professor

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Other areas of specialty/work

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Other areas of specialty/work

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Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of data

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable