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
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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
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target 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
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Mofateh Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 scientific inquiries

Contact

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Associate Professor

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Other areas of specialty/work
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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