Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of Herbal Laxative Capsule on Postoperative Constipation of patients undergoing orthopedic surgery

Protocol summary

Study aim
Determining the effect of Herbal Laxative Capsule on Postoperative Constipation of patients undergoing orthopedic surgery

Design
A clinical trial with a control group, a randomized, and triple blinds. The sample size is 32 in the experimental group and 32 in the control group

Settings and conduct
Consumption of Herbal Laxative Capsule for one week in the experimental group and placebo capsule in the control group. The study site is Beheshti Hospital in Kashan . Patients are not aware of being in the experimental or control group.

Participants/Inclusion and exclusion criteria
Age 18 to 70 years; People who had a normal bowel movement the day before the operation Do not have a problem that prevents cognitive, emotional or verbal communication (ability to communicate with the researcher); Candidate for major orthopedic surgery such as hip joint replacement, hip and proximal hip fractures, etc; Willingness to participate in the study; The same drug and food regimen in the two study groups

Intervention groups
Consumption of Herbal Laxative Capsule in the intervention group and taking placebo capsule in the control group

Main outcome variables
Constipation score and the appearance of stool

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191017045139N1**
Registration date: **2022-08-02, 1401/05/11**
Registration timing: **prospective**
Last update: **2022-08-02, 1401/05/11**
Update count: **0**

Registration date
2022-08-02, 1401/05/11

Registrant information

Name
Mohammadreza Zarei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-20, 1401/05/29

Expected recruitment end date
2022-10-21, 1401/07/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Herbal Laxative Capsule on Postoperative Constipation of patients undergoing orthopedic surgery

Public title
The Effect of Herbal Laxative Capsule on Postoperative Constipation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 70 years People who had a normal bowel movement the day before the operation Do not have a problem that prevents cognitive, emotional or verbal communication (ability to communicate with the researcher). Candidate for major orthopedic surgery such as hip joint replacement, hip and proximal hip fractures, etc. Willingness to participate in the study The same drug and food regimen in the two study groups

Exclusion criteria:

Irregular consumption of capsules Long-term use of drugs such as Narcotic pain relievers, antidepressants, Anti-convulsants, Iron and calcium supplements, Calcium channel blockers, Ibuprofen, and diuretics. Patient discharge earlier than 3 days Having delirium after surgery Incomplete completion of the questionnaire Receiving laxatives The appearance of symptoms of allergy to medicinal plants

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to match the intervention and control groups, the random allocation method will be used, and the participants will be divided into two intervention (herbal laxative capsule) and control (placebo capsule) groups with a 1:1 allocation ratio using random block design with a block size of four. will get By assigning the letter A to the intervention group and the letter B to the control group, 6 states (ABAB, BAAB, BBAA, AABB, BABA, ABBA) are obtained, which are written on separate cards and placed inside a black bag. will be thrown Then randomly one of the cards will be taken out of the bag and the combination of letters on it will be written on a note sheet (AABBABABBBAA...) and that card will be thrown into the container again (selection by placement). Since the sample size in this study was estimated to be 64) participants, the selection will be repeated 16 times and each time the combination written on each removed sheet will be inserted in the sequence of the written order of said sheet. Then, each letter will be assigned a number from 1 to 64 in the order of the letters noted one after the other (A1A2B3B4... B92) and each letter will be placed in an envelope (same shape, same size and same color). And the number of that letter will be written on the envelope [code1=(A), code2=(A), code3=(B), code4=(B), ... code64=(B)]. Inside the envelopes, according to the letter, a combined herbal capsule or placebo will be placed. The envelopes are opened in the order in which the subjects entered the study by the research co-worker and the letter inside the envelope is recorded (the letter A means that the patient is in the intervention group and the letter B means that the patient is in the control group) and then the capsule inside the envelope is Participants will be delivered for one week's use.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study will be designed and conducted in a triple blinded design (Blinding include the participants, the Epidemiologist [data analyst] and the research co-worker [collaborator collecting information]; they will not know about the allocation of participants and the type of intervention applied. If a participant complains of constipation after orthopedic surgery and this person needs intervention from the doctor's point of view, this person will be referred to the research co-worker. The main researcher has allocated the participants based on the order of the codes that have been determined in advance and the envelope number (envelope code 1 = containing herbal capsules, code 2 = containing placebo capsules, ... and envelope code 62 = containing herbal capsules), which should be given to the participants by the research co-worker and then recorded their information. The research co-worker does not know the type of intervention and only gathers information.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Faculty of Medicine & Faculty of Dentistry- Kashan University of Medic

Street address

Kashan University of Medical Sciences, Pezeshk Blvd, Kilometer 3 Qotbe-Ravandi Road, Kashan

City

Kashan

Province

Isfehan

Postal code

8715988141

Approval date

2022-05-08, 1401/02/18

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1401.018

Health conditions studied

1

Description of health condition studied
Postoperative Constipation
ICD-10 code
K59.0
ICD-10 code description
Constipation

Primary outcomes

1

Description
Constipation score
Timepoint
Examining the constipation score after taking the drug on the first, third, fifth, and seventh days after surgery.
Method of measurement
Using the Constipation Assessment Scale [CAS]

2

Description
Stool appearance
Timepoint
Examining the stool appearance after taking the drug on the first, third, fifth, and seventh days after surgery.
Method of measurement
Using the Bristol Stool Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 520 mg Herbal Laxative Capsule (containing 100 mg of Senna alexandrina powder (leaf), 100 mg of Foeniculum vulgare (seed), 100 mg of Aloe Vera L (gum), 100 mg of Carum carvi L. powder(seed) , 100 mg of Coriandrum sativum L. powder (fruit) , 14 mg of Avisel and 6 mg of magnesium stearate. Two capsules should be taken daily (the first 30 minutes before breakfast and the second 30 minutes before lunch) for one week. This capsule is made by Ghaem Daroo Pharmaceutical Company.
Category
Treatment - Drugs

2

Description
Control group: Capsules containing 500 mg of starch powder, 14 mg of Avicel and 6 mg of magnesium stearate made by Ghaem Daroo Pharmaceutical Company.Two capsules should be taken daily (the first 30 minutes before breakfast and the second 30 minutes before lunch) for one week. Those are similar in color and appearance to Herbal Laxative Capsule.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital
Full name of responsible person
Mohammadreza Zarei
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Beheshti Hospital, Pezeshk Blvd, Kilometer 3 Qotbe-Ravandi Road, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Mohammadreza Zarei
Position
Academic instructor
Latest degree
Master
Other areas of specialty/work
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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
No - There is not 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data is sharable when unrecognizable
When the data will become available and for how long
1400
To whom data/document is available
all researcher
Under which criteria data/document could be used
to related research
From where data/document is obtainable
Kashan, Kashan University of Medical Sciences, Vice President of Research and Technology of Kashan University of Medical Sciences, Mr. Dr. Gholam Ali Hamidi, phone number: 03155589399, fax: 03155589338
What processes are involved for a request to access data/document
Submit a written request via fax to receive documents to the Vice President of Research and Technology of Kashan

University of Medical Sciences and after a maximum of one month, receive information about the research

Comments