

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3442 4129

###### Email address

mohammad.zarei3113@yahoo.com

##### 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 (AABBABBBAA...) 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**

Isfahan

**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

##### Street address

Beheshti Hospital, Pezeshk Blvd, Kilometer 3 Qotbe-Ravandi Road, Kashan

##### City

Kashan

##### Province

Isfahan

##### Postal code

8715988141

##### Phone

+98 31 5510 3143

##### Email

mohammad.zarei3113@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Gholam Ali Hamidi

##### Street address

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

##### City

Kashan

##### Province

Isfahan

##### Postal code

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##### Phone

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##### Email

mohammad.zarei3113@yahoo.com

#### 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

Nursery

#### Street address

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

#### City

Kashan

#### Province

Isfahan

#### Postal code

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#### Phone

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mohammad.zarei3113@yahoo.com

## Person responsible for scientific 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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## Person responsible for updating data

### 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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#### Email

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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**