

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

**To determine therapeutic potency of administration of Ziziphus jujuba, Ginseng, and famotidine, against post-surgical adhesion bands in patients with abdominal surgery**

### Protocol summary

#### Study aim

To determine therapeutic potency of administration of Ziziphus jujuba, Ginseng, and famotidine, against post-surgical adhesion bands in patients with abdominal surgery

#### Design

This is a phase II-III clinical trial. Participants will be divided into control versus intervention group receiving Ziziphus jujuba, Ginseng, and famotidine. This is a superiority, parallel, double blinded, randomized study with 100 participants.

#### Settings and conduct

This is a clinical study on abdominal surgery which will be performed in Hospitals of Mashhad University of Medical Sciences. Following surgery, Ziziphus jujuba, Ginseng, and famotidine will be administered consecutively, each for 10 days. This is a double-blinded study in which both participants and data collectors will be blind to the study.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Male or female aged 19 to 60 years who are candidate for two-stage planned operation and provide written documentation of informed consent to participate in the study. Exclusion criteria: Female patients that are pregnant or breastfeeding. Subjects suffering from intra-abdominal abscess. Participants suffering from peritoneum bacterial infection. Drug abuse patients. Participants with Previous abdominal surgery history. Subjects with type I or II Diabetes. Patients suffering from metabolic syndrome. Obese participants with BMI  $\geq 30$

#### Intervention groups

Following abdominal surgery, Ziziphus jujuba, Ginseng, and famotidine will be administered consecutively, each for 10 days

#### Main outcome variables

Frequency of fibrotic adhesion bands formation post

abdominal surgery

### General information

#### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220115053713N3**

Registration date: **2023-01-14, 1401/10/24**

Registration timing: **prospective**

Last update: **2023-01-14, 1401/10/24**

Update count: **0**

#### Registration date

2023-01-14, 1401/10/24

#### Registrant information

##### Name

Seyed Mahdi Hasanian Mehr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 915 203 0439

##### Email address

hasanianmehrm@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2023-02-04, 1401/11/15

#### Expected recruitment end date

2025-02-03, 1403/11/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

To determine therapeutic potency of administration of Ziziphus jujuba, Ginseng, and famotidine, against post-surgical adhesion bands in patients with abdominal surgery

**Public title**

Ziziphus jujuba, Ginseng, and famotidine, against post-surgical abdominal adhesion

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Male or female aged 19 to 60 years Subjects candidate for two-stage planned operation Provide written documentation of informed consent to participate in the study.

**Exclusion criteria:**

Female patients that are pregnant or breastfeeding.  
Subjects suffering from intra-abdominal abscess  
Participants suffering from peritoneum bacterial infection  
Drug abuse Participants with Previous abdominal surgery history  
Subjects with type I-II Diabetes Patients suffering from metabolic syndrome  
Obese participants with BMI  $\geq 30$

**Age**

From **19 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

It is a Block randomized trial in which the Random Allocation Software will be used for allocation concealment which is performed according to SNOSE (sequentially numbered, opaque, sealed envelopes) technique. Envelopes will be sealed and one of the executive member will put randomized number into pockets . Following providing written documentation of informed consent to participate the subjects will pick up a pocket which will be divided into control or intervention group accordingly. Size of Blocks will be four in the study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This is a double-blind clinical trial in which participants and data analyzers will be blinded to the study. It worth noting that participants are aware that they might be randomly categorized either in the treatment or control group. Principal investigator is responsible for safety of

the project, assessing results, and for writing the manuscript is not blinded to final outcomes. Data collectors, Data analyzers will be blinded in this study. Data Safety and Monitoring Board are not blind to data.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Medical School of Mashhad  
University of Medical Sciences

**Street address**

Azadi Sq.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9197985174

**Approval date**

2022-09-13, 1401/06/22

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1401.453

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

Intestinal adhesions [bands] with obstruction  
(postprocedural) (postinfection)

**ICD-10 code**

K56.5

**ICD-10 code description**

Intestinal adhesions [bands] with obstruction  
(postprocedural) (postinfection)

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

Comparing frequency of adhesion bands in the presence and absence of the treatment

**Timepoint**

Between the 1st and the 2nd surgery

**Method of measurement**

Based on Zuhlke scoring system

## 2

### **Description**

Comparing thickness of adhesion bands in the presence and absence of treatment

### **Timepoint**

Between the 1st and the 2nd surgery

### **Method of measurement**

Based on Zuhlke scoring system

## 3

### **Description**

Comparing angiogenesis of adhesion bands in the presence and absence of treatment

### **Timepoint**

Between the 1st and the 2nd surgery

### **Method of measurement**

Based on Zuhlke scoring system

## 4

### **Description**

Bowel obstruction due to adhesion band formation

### **Timepoint**

Between the 1st and the 2nd surgery

### **Method of measurement**

Macroscopic evaluation by surgeon

## **Secondary outcomes**

## 1

### **Description**

Any side effect in the intervention group

### **Timepoint**

Between the 1st and the 2nd surgery

### **Method of measurement**

Analyzed by lab results and clinical outcomes

## 2

### **Description**

Need to re-surgery

### **Timepoint**

Within a year post-operation

### **Method of measurement**

Clinical symptoms

## 3

### **Description**

Rate of mortality post-surgery

### **Timepoint**

Within a year post-operation

### **Method of measurement**

Surgeon evaluation

## 4

### **Description**

Presence of infection, abscess, and sepsis post-surgery

### **Timepoint**

Within a year post-operation

### **Method of measurement**

Analyzed by lab results and clinical outcomes

## **Intervention groups**

## 1

### **Description**

Control group: The control group will receive routine surgery process and placebo of Ziziphus jujuba, Ginseng, and famotidine will be given to them. Time, Form, and dose of placebo is based on the intervention group, which is explained in below.

### **Category**

Placebo

## 2

### **Description**

Intervention group: Following abdominal surgery, Ziziphus jujuba, Ginseng, and famotidine will be administered consecutively, each for 10 days. Administration dose of Ginseng, famotidine, and Ziziphus jujuba is 2 gram, 40 mg, and 30 gram respectively. Ginseng, Fmotidine, and Ziziphus jujuba will be given in capsule, tablet, and sachet, respectively.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Mashhad University of Medical Sciences, Surgery  
Department of Mashhad Medical university Hospitals

#### **Full name of responsible person**

Seyed Mahdi Hassanian Mehr

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+98 915 203 0439

#### **Email**

hasanianmehrm@mums.ac.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Mashhad University of Medical Sciences

#### **Full name of responsible person**

Majid Ghayour-Mobarhan

**Street address**  
Azadi Sq.

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GhayourM@mums.ac.ir

**Grant name**

**Grant code / Reference number**  
4000805

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Mashhad 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**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Seyed Mahdi Hassanian Mehr

**Position**  
Associate Professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Biochemistry

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
Associate Professor

**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Seyed Mahdi Hassanian Mehr

**Position**  
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**Latest degree**  
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**Other areas of specialty/work**  
Biochemistry

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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

Yes - There is 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

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

We will be ready to share all the collected de-identified participant data (IPD) to other researchers after the end of study.

**When the data will become available and for how long**

Sharing of all collected de-identified participants data (IPD) will be started immediately after publication.

**To whom data/document is available**

All collected de-identified participants data (IPD) will be shared to people working either in academic institutions or business companies upon their request.

**Under which criteria data/document could be used**

The collected de-identified participants data (IPD) will be

only shared to those recipients who commit themselves to use them only for patients. They also should commit themselves to share these data with other organization only after asking permission from the original source

**From where data/document is obtainable**

Data/Documents will be obtainable by sending an e-mail to hasanianmehr@ums.ac.ir

**What processes are involved for a request to access data/document**

The applicant who wish to have access to document/data files should send an e-mail to hasanianmehr@ums.ac.ir commit him/herself to not to share these documents with others unless asking permission from the original source. Next, document/data will be sent to him/her by e-mail immediately.

**Comments**