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 ≥ 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 ≥ 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour-Mobarhan

Street address
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Razavi Khorasan
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9197985174
Phone
+98 915 203 0439
Email
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

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Person responsible for updating data

Contact

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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 paticipant 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 hasanianmehrm@mums.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 hasanianmehrm@mums.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