

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Ameliorative effect of Ziziphus jujube, Ginseng, and punica in decreasing adhesion band formation in patients suffering from endometriosis

Protocol summary

Study aim

To study the ameliorative effect of Ziziphus jujube, Ginseng, and punica in decreasing adhesion band formation in patients suffering from endometriosis

Design

This is a phase II-III clinical trial. Participants will be divided into control versus intervention group receiving Ziziphus jujuba, Ginseng, and Punica. This is a superiority, parallel, double blinded, randomized study with 50 participants.

Settings and conduct

This is a clinical study on endometriosis which will be performed in Hospitals of Mashhad University of Medical Sciences. In the intervention group, along with standard treatment, Ziziphus jujuba, Ginseng, and Punica will be administered consecutively, each for 7 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: Women patient's diagnosed with endometriosis, Aged 19 to 60 years old, Exclusion criteria: Patients that are pregnant or breastfeeding, Drug abuse, Subjects with type I-II Diabetes, Patients suffering from metabolic syndrome, Obese participants with BMI \geq 30, Patients suffering from cancer, Subjects with blood clotting disorders.

Intervention groups

Intervention group: When patient is diagnosed with endometriosis, Ziziphus jujuba, Ginseng, and punica will be administered consecutively, each for 7 days. Administration dose of Ginseng, punica, and Ziziphus jujuba is 2 gram, 1 gram, and 30 gram respectively. Ginseng, punica, and Ziziphus jujuba will be given in capsule, capsule, and sachet, respectively. The control group will receive placebo instead of Ziziphus jujuba, Ginseng, and punica. Color, time, Form of the placebo is similar to the intervention

Main outcome variables

Frequency of fibrotic adhesion bands formation, Pattern

of menstruations cycle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220115053713N4**

Registration date: **2023-07-16, 1402/04/25**

Registration timing: **prospective**

Last update: **2023-07-16, 1402/04/25**

Update count: **0**

Registration date

2023-07-16, 1402/04/25

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

2023-09-01, 1402/06/10

Expected recruitment end date

2025-09-01, 1404/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ameliorative effect of Ziziphus jujube, Ginseng, and punica in decreasing adhesion band formation in patients suffering from endometriosis

Public title

To study the role of Ziziphus jujube, Ginseng, and punica in patients suffering from endometriosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women patient's diagnosed with endometriosis Aged 19 to 60 years Provide written documentation of informed consent to participate in the study.

Exclusion criteria:

Patients that are pregnant or breastfeeding. Drug abuse
Subjects with type I-II Diabetes Patients suffering from metabolic syndrome Obese participants with BMI ≥ 30
Patients suffering from cancer Subjects with blood clotting disorders

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

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 . Depending on the information inside the pocket, the applicant will be either in the control or the intervention group. Following providing written documentation of informed consent to participate the subjects will randomly 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

In this clinical trial participants will be blinded to the study. Color, shape, and type of administration of the placebo is similar to the intervention, in order to provide blindness to the participants. Data collectors, Data analyzers will be blinded in this study.

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

Masshad

Province

Razavi Khorasan

Postal code

9197985174

Approval date

2023-02-04, 1401/11/15

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.687

Health conditions studied

1

Description of health condition studied

Endometriosis of uterus

ICD-10 code

N80.0

ICD-10 code description

Endometriosis of uterus

Primary outcomes

1

Description

Amount of adhesion band

Timepoint

1 to 3 months post-treatment

Method of measurement

Based on the rASRM scoring system

Secondary outcomes

1

Description

Pattern of menstruations cycle

Timepoint

1 to 3 months post-treatment

Method of measurement

Analyzed by physician menstruations cycle including

amenorrhoea, hypomenorrhoea, and dysmenorrhoea

Intervention groups

1

Description

Control group: The control group will receive placebo instead of Ziziphus jujuba, Ginseng, and punica. Color, time, Form of the placebo is similar to the intervention.

Category

Placebo

2

Description

Intervention group: When patient is diagnosed with endometriosis, Ziziphus jujuba, Ginseng, and punica will be administered consecutively, each for 7 days. Administration dose of Ginseng, punica, and Ziziphus jujuba is 2 gram, 1 gram, and 30 gram respectively. Ginseng, punica, and Ziziphus jujuba will be given in capsule, capsule, and powder, respectively. Ginseng and Punica will be provided by the Goldaroo Company and powder of Ziziphus will be prepared by the Pharmacy School of the Mashhad University of Medical Sciences.

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

Street address

Azadi Sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9197985174

Phone

+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.

City

Mashhad

Province

Razavi Khorasan

Postal code

9197985174

Phone

+98 51 3800 2355

Email

GhayourM@mums.ac.ir

Grant name

Mashhad University of Medical Sciences

Grant code / Reference number

4011736

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

Street address

Azadi Sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9197985174

Phone

+98 51 3800 2355

Email

hasanianmehrm@mums.ac.ir

Person responsible for scientific 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

Street address

Azadi Sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9197985174

Phone

+98 51 3800 2355

Email

hasanianmehrm@mums.ac.ir

hasanianmehrm@mums.ac.ir

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 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.

Comments**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

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Azadi Sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3800 2355

Email