

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on symptoms, mass size and doppler indices of uterine arteries in patients with uterine fibroids

Protocol summary

Study aim

Evaluation of the effect of Acupuncture on patients with uterine fibroids

Design

Randomized, superiority, parallel, three group trial (2 intervention and one control group) with 24 patients in each group, single blinded, Randomization type: Block, Method used to generate the random allocation sequence: envelope

Settings and conduct

Location :Acupuncture clinic of Imam Reza hospital in Mashhad. Patients, analyzers, statisticians and radiologist will be blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: non virgin females aged 18 until menopause-having uterine fibroids type 1-6 according to contemporary medicine standards-signing the informed consent form-no need for emergency surgery intervention-able to come to acupuncture clinic twice a week for 8 weeks-not having adenomyosis or other genitourinary malignancies, severe heart / hepatic / renal failure, epilepsy, uncontrolled diabetes and hypertension-non pregnant and not breastfeeding-not consuming hormonal drugs and drugs affecting results of this study since 3 months ago-not participating in other acupuncture based studies-non smokers, not consuming alcohol-not having Hb bellow 10 mg/d Exclusion criteria: 1-mismatching with the inclusion criteria after the start of the intervention -getting adenomyosis, genitourinary malignancies, severe heart/ hepatic/ renal failure and seizure during the study-not willing to get acupuncture for any reason-being absent from more than two consecutive sessions-getting pregnant during the study

Intervention groups

Segmental Electroacupuncture group, Manual Acupuncture group, Sham Acupuncture group

Main outcome variables

Tumor size, diameter, pulsatility index and resistance index of uterine arteries

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110809007265N14**

Registration date: **2023-11-01, 1402/08/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-01, 1402/08/10**

Update count: **0**

Registration date

2023-11-01, 1402/08/10

Registrant information

Name

Hoda Azizi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-01, 1402/08/10

Expected recruitment end date

2024-03-20, 1403/01/01 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty	Randomization type: Block The method used to generate the random allocation sequence: envelope method: The envelopes will be prepared and printed by a member of the research team and random numbers with the help of Randomaize.com site, and placed inside the envelope. The lid of the envelopes will be closed and its contents will not be visible from the outside. Then the purpose of the study will be explained to the person who meets the stated conditions, and if the person wishes to continue, he will sign the informed consent form and pick an envelope, then opens it, and based on the contents of the envelope, the person will be entered into the intervention or control group. Allocation Concealment method: Numbered sealed envelopes After randomly assigning each patient to one of the groups, the name of the patient and the corresponding group is recorded in a book by the allocator who will not be among the evaluators.
Scientific title Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on symptoms, mass size and doppler indices of uterine arteries in patients with uterine fibroids	Blinding (investigator's opinion) Single blinded
Public title Evaluation and comparison of the effects of electroacupuncture and manual acupuncture on uterine fibroids	Blinding description The patients are blinded in all stages of the intervention and do not know which group they have participated in. The main researcher who performs acupuncture knows the group of patients because the treatment protocol of each group is different from the other group. The statistical researcher and analyzer, the radiologist who performs ultrasound Doppler and the gynecologist, who is responsible for the initial diagnosis of patients and their referral, are also blind to the groups.
Purpose Treatment	Placebo Used
Inclusion/Exclusion criteria Inclusion criteria: Non virgin females aged 18 until menopause Females who have uterine fibroids type 1-6 according to contemporary medicine standards Signing the informed consent form No need for immediate or emergency surgery intervention Being able to come to acupuncture clinic twice a week for 8 weeks Not suffering from adenomyosis or other genitourinary malignancies Non pregnant and not breastfeeding Not consuming hormonal drugs and drugs which can affect results of this study since 3 months ago Not suffering from severe heart / hepatic / renal failure No history of epilepsy Not participating in other acupuncture based studies Non smokers, not consuming alcohol Not suffering from uncontrolled diabetes and Hypertension Not having Hb bellow 10 mg/dl Exclusion criteria: Mismatching with the inclusion criteria after the start of the intervention (such as the need to take hormonal drugs or emergency surgery) Getting adenomyosis, genitourinary malignancies, severe heart/ hepatic/ renal failure and seizure during the study Not willing to get acupuncture for any reason Being absent from more than two consecutive treatment sessions Getting pregnant during the study	Assignment Parallel Other design features
Age From 18 years old Gender Female Phase 3 Groups that have been masked - Participant - Outcome assessor - Data analyser Sample size Target sample size: 72 Randomization (investigator's opinion) Randomized Randomization description	Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of Mashhad university of medical sciences Street address Daneshgah street, Ghorashi building (central building of Mashhad university of medical sciences) City Mashhad Province Razavi Khorasan Postal code 91357345 Approval date 2023-10-22, 1402/07/30 Ethics committee reference number IR.MUMS.REC.1402.216

Health conditions studied

1

Description of health condition studied

Leiomyoma

ICD-10 code

D25 Leiomy

ICD-10 code description

A benign smooth muscle neoplasm arising from the body of the uterus. It is characterized by the presence of spindle cells with cigar-shaped nuclei, interlacing fascicles, and a whorled pattern. Uterine fibroids are the most common non-cancerous tumors in w

Primary outcomes

1

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on mass size of dominant uterine fibroids before, immediately after intervention and in a 2 month follow-up

Timepoint

Before, immediately after intervention, 2 month after intervention

Method of measurement

Transvaginal doppler ultrasound

2

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on resistance index of uterine arteries before, immediately after intervention and in a 2 month follow-up

Timepoint

Before, immediately after intervention, 2 month after intervention

Method of measurement

Transvaginal doppler ultrasound

3

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on pulsatility index of uterine arteries before, immediately after intervention and in a 2 month follow-up

Timepoint

Before, immediately after intervention, 2 month after intervention

Method of measurement

Transvaginal doppler ultrasound

4

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on diameter of uterine arteries before, immediately after intervention and in a 2 month follow-up

Timepoint

Before, immediately after intervention, 2 month after intervention

Method of measurement

Transvaginal doppler ultrasound

Secondary outcomes

1

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on intensity and regularity of menstrual bleeding in patients with uterine fibroids before, immediately after intervention and in in a 2 month follow-up

Timepoint

before, immediately after intervention and in in a 2 month follow-up

Method of measurement

UFS-QOL questionnaire

2

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on pelvic tightness or pressure in patients with uterine fibroids before, immediately after intervention and in in a 2 month follow-up

Timepoint

before, immediately after intervention and in in a 2 month follow-up

Method of measurement

UFS-QOL questionnaire

3

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on frequent urination during daytime in patients with uterine fibroids before, immediately after intervention and in in a 2 month follow-up

Timepoint

before, immediately after intervention and in in a 2 month follow-up

Method of measurement

UFS-QOL questionnaire

4

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on frequent nighttime urination in patients with uterine fibroids before, immediately after

intervention and in in a 2 month follow-up

Timepoint

before, immediately after intervention and in in a 2 month follow-up

Method of measurement

UFS-QOL questionnaire

5

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on feeling fatigued in patients with uterine fibroids before, immediately after intervention and in in a 2 month follow-up

Timepoint

before, immediately after intervention and in in a 2 month follow-up

Method of measurement

UFS-QOL questionnaire

6

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on concerns of patients with uterine fibroids before, immediately after intervention and in in a 2 month follow-up

Timepoint

before, immediately after intervention and in in a 2 month follow-up

Method of measurement

UFS-QOL questionnaire

7

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on activities of patients with uterine fibroids before, immediately after intervention and in in a 2 month follow-up

Timepoint

before, immediately after intervention and in in a 2 month follow-up

Method of measurement

UFS-QOL questionnaire

8

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on energy and mood of patients with uterine fibroids before, immediately after intervention and in in a 2 month follow-up

Timepoint

before, immediately after intervention and in in a 2 month follow-up

Method of measurement

UFS-QOL questionnaire

9

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on control in patients with uterine fibroids before, immediately after intervention and in in a 2 month follow-up

Timepoint

before, immediately after intervention and in in a 2 month follow-up

Method of measurement

UFS-QOL questionnaire

10

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on self-consciousness in patients with uterine fibroids before, immediately after intervention and in in a 2 month follow-up

Timepoint

before, immediately after intervention and in in a 2 month follow-up

Method of measurement

UFS-QOL questionnaire

11

Description

Evaluation and comparison of the effects of Segmental Electroacupuncture, Manual Acupuncture and Sham Acupuncture on sexual function in patients with uterine fibroids before, immediately after intervention and in in a 2 month follow-up

Timepoint

before, immediately after intervention and in in a 2 month follow-up

Method of measurement

UFS-QOL questionnaire

Intervention groups

1

Description

First Intervention group: In the segmental electroacupuncture group, after inserting the needles in their predefined acupoints (two points located on the abdominal myotomes with common innervation with the uterine nerves: ST28 (Shuidao) & ST29 (Guilai) located on myotomes T12/L1 and two points located on the distal myotomes with common innervation with the uterine nerves: SP6 (Sanyinjiao) located on S2 myotome & LIV3 (Taichong) located on S3 myotome) Bilaterally and reaching De Qi, the needles will be connected to the electroacupuncture (electrical stimulation) device (abdominal points on each side together and distal points on each side together) and will be stimulated for thirty minutes with a frequency of eighty hertz and a wavelength of one hundred And eighty microseconds and with continuous mode. The intensity of the electric

current starts from three milliamps and can be increased until the patient does not feel pain.

Category

Treatment - Devices

2**Description**

Second Intervention group: In the manual acupuncture group, after inserting the needles in the specified acupoints and reaching De Qi, the needles will remain in place for thirty minutes without stimulation. acupoints of this group: LU7 (Lieque) right hand, ST25 (Tianshu), ST28 (Shuidao), ST36 (Zusanli), ST40 (Fenglong), SP4 (Gongsun) right foot, SP6 (Sanyinjiao), SP10 (Xuehai), KI6 (Zhaohai) left foot, KI14 (Siman), PC6 (Neiguan) left hand, LIV3 (Taichong), LIV8 (Ququan), CV 3 (Zhongji), CV4 (Guanyuan), CV6 (Qihai), EX-CA1 (Zigong), N-CA-18 (Tituo) In order to maintain the blinding process, the needles will be connected to the electroacupuncture device in a similar way to the first group, but no stimulation will be induced and we will only use the beep sound of the device.

Category

Treatment - Devices

3**Description**

Control group: In Sham acupuncture group, Streitberger placebo needles will be used bilaterally in the same points as in segmental electric acupuncture group. These needles do not have the ability to penetrate the skin and will enter into their handle after a gentle tap while placing them on the skin. the needle handle will be connected to the electroacupuncture machine in the same way as the electroacupuncture group, with the difference that no stimulation is induced and we will only use the beep sound of the machine to resemble the electroacupuncture model and maintain the blinding process.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Acupuncture clinic, Imam Reza hospital, Mashhad, Iran

Full name of responsible person

Hoda Azizi

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Web page address**Grant name****Grant code / Reference number****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

Elham Hooshyarazar

Position

PhD candidate

Latest degree

Medical doctor

Other areas of specialty/work

Acupuncture

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Person responsible for scientific inquiries

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information on primary outcomes and secondary outcomes can be shared from the Participant Data File item. The study protocol and clinical study report will be published in full The informed consent form can be shared in raw form

When the data will become available and for how long

The protocol is ready to be published Other documents are going to be published after the survey is finished

To whom data/document is available

University professors, university students and researchers

Under which criteria data/document could be used

Application of data in order to use them in future surveys and also their application in treatment of patients

From where data/document is obtainable

Dr.Hoda Azizi (azizih@mums.ac.ir) Dr.Elham Hooshyarazar (hooshyare991@mums.ac.ir)

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

An e-mail is needed to be sent to the above mentioned persons

Comments