

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effect of Iranian medicine based on spider and acupuncture on sperm parameters, some inflammatory factors and sex hormones in men with idiopathic infertility: a randomized, one-way clinical trial

#### Protocol summary

##### Study aim

Comparison of the effect of Iranian medicinal product based on carob and acupuncture using electrical stimulation on sperm motility, some inflammatory factors and sex hormones in men with idiopathic infertility

##### Design

A clinical trial with a standardized control group and two parallel one-way blind randomized groups

##### Settings and conduct

Infertile men referred to Urology Clinic of Ghaem Hospital and Milad Infertility Treatment Center in Mashhad, Iran. If they have conditions for entering the study They are randomly assigned to one of three study groups The evaluated variables are evaluated and recorded in the two phases before and after the study

##### Participants/Inclusion and exclusion criteria

Including criteria: Patient's desire Passing for at least one year after the decision to give birth and not using contraceptives 20-45 year old men Reduction in sperm motility Normal values of gonadotropins, testosterone and serum prolactin Exclusive criteria: Infection of the genital system; anatomical abnormalities in the genital system such as varicocele from the operation or not, cryptorchidism and ...; systemic diseases or medical treatment in the last three months; history of surgical procedures on the testes and Vas deferens; ICSI candidate patients ; contact with pesticides, heavy metals and solvents; use of antioxidant supplementation in the past three months and coagulation disorders, infection, eczema at the site of needle and phobias From the needle

##### Intervention groups

Control group - two tablets of 400 mg pentoxifylline per day for three months. Iranian medicine group- three oral cups of 800 mg drug based Carob per day for three months each day. Acupuncture group-The treatment

duration was 16 sessions over a period of 3 months.

##### Main outcome variables

Sperm count - sperm motility - sperm morphology- Testosterone,FSH,LH,Prolactin Malondialdehyde, CRP

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171031037132N2**

Registration date: **2019-03-11, 1397/12/20**

Registration timing: **prospective**

Last update: **2019-03-11, 1397/12/20**

Update count: **0**

##### Registration date

2019-03-11, 1397/12/20

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3601 7466

##### Email address

ahmadianm1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-04, 1398/01/15

##### Expected recruitment end date

2019-10-07, 1398/07/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of Iranian medicine based on spider and acupuncture on sperm parameters, some inflammatory factors and sex hormones in men with idiopathic infertility: a randomized, one-way clinical trial

**Public title**

Comparison of the effect of Iranian medicine based on spider and acupuncture on sperm parameters, some inflammatory factors and sex hormones in men with idiopathic infertility: a randomized, one-way clinical trial

**Purpose**

Treatment

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

Willingness to cooperate Passing for at least one year from the time you decide to give birth and not use contraceptives Men aged 20-45 Concerning the decline in sperm motility with unknown cause based on WHO criteria (less than 50% sperm motility) Normal levels of gonadotropins, testosterone and serum prolactin

**Exclusion criteria:**

Infection of the genital system anatomical abnormalities in the genital system such as varicocele from the operation and not, cryptorchidism and ... systemic diseases or drug treatments in the last three months History of surgical procedures on the testes and vas deferens Patients with ICSI candidate due to severe spermogram disorder and presence of other infertility factors Contact with pesticides, heavy metals and solvents; use of antioxidant supplement in the last three months Coagulation disorders, infection, eczema at the site of needle and phobia from the needle

**Age**

From **20 years** old to **45 years** old

**Gender**

Male

**Phase**

3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **51**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random assignment will be done using the PASS software, and the individuals will be assigned in the assigned groups according to their order of entry. The envelopes are prepared by a research team member and, with the help of random numbers, arrange the arrival of individuals into groups, which will be packaged with the help of the PASS software and will be printed

inside the envelope. Pocket doors will be closed and its contents are not visible from the outside.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, the patient is not blind to his treatment method in relation to his group, this situation is true for the main investigator and therapists, but data collection and follow-up officials have been blinded to study groups.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

The Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Mashhad University Of Medical Sciences, University Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

13944-91388

**Approval date**

2019-01-26, 1397/11/06

**Ethics committee reference number**

IR.MUMS.REC.1397.266

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

Male infertility

**ICD-10 code**

N46

**ICD-10 code description**

Male infertility

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

Sperm motility

**Timepoint**

Before the start of the study and three months after the start of the intervention

**Method of measurement**

Spermogram

**2****Description**

Sperm count

**Timepoint**

Before the start of the study and three months after the start of the intervention

**Method of measurement**

Spermogram

**3****Description**

Sperm morphology

**Timepoint**

Before the start of the study and three months after the start of the intervention

**Method of measurement**

Spermogram

**4****Description**

Prolactin hormone

**Timepoint**

Before the start of the study and three months after the start of the intervention

**Method of measurement**

Elisa Reader

**5****Description**

Testosterone hormone

**Timepoint**

Before the start of the study and three months after the start of the intervention

**Method of measurement**

Elisa Reader

**6****Description**

Luteinizing hormone

**Timepoint**

Before the start of the study and three months after the start of the intervention

**Method of measurement**

Elisa Reader

**7****Description**

Follicle stimulating hormone

**Timepoint**

Before the start of the study and three months after the start of the intervention

**Method of measurement**

Elisa Reader

**8****Description**

Malondialdehyde

**Timepoint**

Before the start of the study and three months after the start of the intervention

**Method of measurement**

Elisa Reader

**9****Description**

C-Reactive Protein

**Timepoint**

Before the start of the study and three months after the start of the intervention

**Method of measurement**

Elisa Reader

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control group: Two tablets of 400 mg of pentoxifylline ( Manufactured by Hakim Pharmaceutical Company. Tehran-Iran) will be taken daily for three months each day

**Category**

Treatment - Drugs

**2****Description**

Intervention group1: Patients receive three 800 mg capsules (including Ceratonia siliqua, Cinnamomum verum and Tribulus terrestris) for three months each day.

**Category**

Treatment - Drugs

**3****Description**

Intervention group2: Patients undergo acupuncture for 16 sessions over a three month period.The first week of the week is 2 sessions, the next 2 months are weekly 1 session and a total of 16 sessions. Acupuncture points include:CV4, CV2, BL23, BL52, KI 3, KI 6, KI 7, SP6, SP9, LI 4, LI 11, LV3, ST28, ST 30 . And the Ren 2 and Ren 4 points are connected to the electro-acupuncture device.

**Category**

Treatment - Devices

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Alireza Akhavan Rezayat

**Street address**

Ahmadabad Abad Street, Ghaem Hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91766-99199

**Phone**

+98 51 3840 0000

**Email**

Quaem.Medical.Center@mums.ac.ir

**Web page address**

<http://quaem.mums.ac.ir/>

## 2

### Recruitment center

**Name of recruitment center**

Milad Infertility Research and Treatment Center

**Full name of responsible person**

Mohammad Ahmadian

**Street address**

East Razi Street, Milad Infertility Research and Treatment Center

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91359 13556

**Phone**

+98 51 3853 4021

**Email**

ivfcenter@mums.ac.ir

**Web page address**

<http://ivfcenter.mums.ac.ir/index.php>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Mashhad University of Medical Sciences, University Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

13944-91388

**Phone**

+98 51 3841 2081

**Email**

vcresearch@mums.ac.ir

**Web page address**

<http://v-research.mums.ac.ir/>

**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**

Hamidreza Bahrami Taghanaki

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Chinese medicine

**Street address**

End of Sanabad Street, Deputy of Health of Mashhad University of Medical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9185684538

**Phone**

+98 51 3841 5001

**Email**

BahramiHR@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohammad Ahmadian

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Azadi Square, Campus University, Faculty of Iranian and Complementary Medicine

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3884 8931

**Email**

Ahmadianm1@mums.ac.ir

Medical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3884 8931

**Email**

Ahmadianm1@mums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

Undecided - It is not yet known if there will be 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**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohammad Ahmadian

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Iranian traditional medicine

**Street address**

Azadi Square, Campus University, Faculty of Iranian and Comprehensive Medicine, Mashhad University of