Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 medicial 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- Testosteron,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 Univercity 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

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 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