

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation the effect of laser acupuncture on semen analysis parameters in oligospermic patients

Protocol summary

Study aim

The effect of laser acupuncture on male fertility in oligospermia

Design

The clinical trial has a control group with a parallel, double-blind, randomized group on 72 patients. After the intervention, the number of semen samples taken from all patients is 3 samples.

Settings and conduct

Patients in the intervention group underwent laser acupuncture twice a week for two consecutive 5 weeks which is performed by a trained technician of acupuncture and lasers. In the control group, laser acupuncture is performed as sham acupuncture. The intervention is performed in the laser research center of Shohadaye Tajrish Hospital in Tehran. Both patients and technicians are blinded.

Participants/Inclusion and exclusion criteria

The criteria for entering the study are those under 35 years of age, at least one year of unsuccessful attempts without contraception, oligospermia. Criteria for not entering the study include azoospermia, a history of infertility-related urological surgery, a history of hormonal and genetic disorders, a history of taking complementary hormonal medications over the past year, and a varicocele on examination or ultrasonography, history of undescended testis, history of mumps and epididymo-orchitis, history of medical diseases (diabetes, hypertension, hyperlipidemia, thyroid disorders, etc.), abnormal findings of the testis examination, history of smoking, alcohol and drugs, as well as history of occupational exposure With chemicals and radioactivity.

Intervention groups

Patients in the intervention group undergo laser acupuncture twice a week for two consecutive 5-week periods. The intervention is in the form of energy transfer by laser fibers to the specified points (acupoint). Control group: Sham laser acupuncture is performed while the

device is off.

Main outcome variables

Semen volume; Total sperm count; Sperm motility; Sperm concentration; Sperm morphology

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200624047907N1**

Registration date: **2020-10-26, 1399/08/05**

Registration timing: **retrospective**

Last update: **2020-10-26, 1399/08/05**

Update count: **0**

Registration date

2020-10-26, 1399/08/05

Registrant information

Name

Vahid Shahabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 25719

Email address

khafash88@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of laser acupuncture on semen analysis parameters in oligospermic patients

Public title

Effect of laser acupuncture on semen analysis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age under 35 at least one year effort without contraceptions oligospermia

Exclusion criteria:

history of surgeries in associating infertility(varicocelectomy, inguinal hernia repair, undescended testis repair) history of hormonal and genetic disorder history of taking hormonal medicines during last year varicocele found via examination or ultrasonography history of undescended testis history of mumps and epididymo-orchitis history of medical diseases(DM, hypertension, dyslipidemia and so on) abnormal finding in testis examination history of smoking, alcoholism and using opioids exposure to chemical and radioactive materials

Age

From **18 years** old to **35 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Before starting the study, sealed envelopes are provided which indicate the person's control or intervention group. Each person who enters the study selects an envelope and enters the control or intervention group based on it.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both participants and researchers are unaware of the allocation of study groups. The technician of the laser is the only one who is aware of the allocation of study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahrdari Ave.

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2019-12-29, 1398/10/08

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.472

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

male infertility

ICD-10 code

N46.9

ICD-10 code description

Male infertility, unspecified

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

semen volume

Timepoint

The first sample before the intervention, the second sample immediately after the intervention and the third sample three months after the intervention are taken

Method of measurement

Laboratory experiment

2**Description**

Sperm motility

Timepoint

The first sample before the intervention, the second sample immediately after the intervention and the third sample three months after the intervention are taken

Method of measurement

Laboratory experiment

3

Description

Sperm concentration

Timepoint

The first sample before the intervention, the second sample immediately after the intervention and the third sample three months after the intervention are taken

Method of measurement

Laboratory experiment

4

Description

Sperm morphology

Timepoint

The first sample before the intervention, the second sample immediately after the intervention and the third sample three months after the intervention are taken

Method of measurement

Laboratory experiment

Secondary outcomes

1

Description

Fertility

Timepoint

Any time after the intervention is completed

Method of measurement

Follow up the patient through questioning

Intervention groups

1

Description

Intervention group: Patients in the intervention group undergo laser acupuncture twice a week for two consecutive 5-week periods. The intervention is in the form of energy transfer by laser fibers to the specified points (acupoint) which is performed by a trained technician of acupuncture and lasers via Canadian optic and laser center laser device

Category

Treatment - Devices

2

Description

Control group: Sham laser acupuncture is performed while the device is off. This procedure is performed twice a week for two consecutive 5-week periods.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish hospital

Full name of responsible person

Farzad Allameh

Street address

Shahrdari Ave.

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Phone

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Email

farzadallame@gmail.com

Web page address

<http://shmc.sbmu.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

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Province

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Postal code

1985717443

Phone

+98 21 2243 9780

Email

Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vahid Shahabi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Urology ward, Shohadaye Tajrish hospital, Shahr-dari Ave., Tajrish, Tehran

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Tehran

Province

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Postal code

1989934148

Phone

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Fax**Email**

khafash88@gmail.com

Person responsible for scientific inquiries

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Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vahid Shahabi

Position

Resident

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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

The final results of the study will be fully available.

When the data will become available and for how long

After the end of the study-from 2021

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

The final results of the study will be fully available.

From where data/document is obtainable

Farzad Allameh -Urology Department, Ground Floor, Building No. 1, Shohadaye Tajrish Hospital, Shahr-dari Ave., Tehran, Iran email: farzadallame@gmail.com

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

Via email Request - 2 weeks

Comments