Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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Tehran
Postal code
1989934148
Phone
+98 21 25719
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
City
Tehran
Province
Tehran
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, Shahrdari Ave., Tajrish, Tehran

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Person responsible for updating data

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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, Shahrdari Ave., Tehran, Iran email: farzadallame@gmail.com

What processes are involved for a request to access data/document
Via email Request - 2 weeks

Comments