

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The Effectiveness of Autologous Platelet-Rich Plasma (PRP) and laser acupuncture in the Therapy of Infertile Men with Non-Obstructive Azoospermia

Protocol summary

Study aim

Survey of effectiveness of autologous platelet-rich plasma and low-power laser in the treatment of male infertility

Design

Eligible men referring to infertility clinics are divided into three groups. All patients are given a consent form. Patients in the first group are injected with PRP intratesticularly and receive laser acupuncture twice a week for 4 consecutive weeks. Second group, PRP is injected once, and the third group is considered as a control group without any intervention. To perform PRP, platelet-rich plasma is collected from fresh whole blood from a peripheral vein, stored in acid-citrate dextrose A (ACD-A) anticoagulant solution, and to increase platelets, autologous blood is centrifuged using a kit, and PRP equipment is processed. The intervention is in the form of energy transfer by laser acupuncture and PRP injection on specified points performed. The semen samples taken before the start of the intervention, immediately after the end of the intervention and three months after the end of the intervention.

Settings and conduct

Shahada Tajrish Hospital and Skin and Stem Cell Research Center

Participants/Inclusion and exclusion criteria

Men under 45 years old with non-obstructive azoospermia, which pathology is confirmed from testicular tissue, and have the history of problems and genetics, drug use during the past year, the presence of varicocele in the examination or ultrasound, the presence of Sertoli cell syndrome in the testicular biopsy report, the absence of testicular descent, the history of acute epididymitis, abnormal examination of the testicles, and also . They were not the risk of having a job with chemical and radioactive materials and obstructive azoospermia.

Intervention groups

1- First intervention group: PRP 2- Second intervention group: PRP and laser 3- Control group

Main outcome variables

sperm motility, concentration and morphology of semen, Sperm count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111121008146N43**

Registration date: **2023-05-06, 1402/02/16**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-06, 1402/02/16**

Update count: **0**

Registration date

2023-05-06, 1402/02/16

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8021

Email address

laser.cntr@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Autologous Platelet-Rich Plasma (PRP) and laser acupuncture in the Therapy of Infertile Men with Non-Obstructive Azoospermia

Public title

Efficacy of autologous platelet-rich plasma and laser acupuncture in the treatment of non-obstructive azoospermia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age less than 45 years non-obstructive azoospermia with testicular pathology tissue confirmation

Exclusion criteria:

History of hormonal and genetic disorders History of taking hormonal supplements during the last year Presence of varicocele in examination or ultrasound Presence of Sertoli cell-only syndrome report in testicular biopsy report History of undescended testicles History of acute epididymo-orchitis Abnormal examination of testicles History of occupational exposure to chemical and radioactive substances Obstructive azoospermia.

Age

To 45 years old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trial study, 45 patients with infertility randomly will be included in the study. For the random allocation of individuals in the study groups, the method of random allocation with block method (Block Randomization) will be used. In this method, blocks with a size of 9 (5 blocks) with a ratio of 1: 1 will be used. Random Allocation software version 2 will be used to generate random sequences. The random allocation concealment method is used in such a way that random sequences are created. In this method, they are identified on the cards and these cards are placed inside the sealed envelopes in order. To maintain the created sequence, the numbering will be done on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then, according to the order of entry of the eligible participants, the

envelopes will be opened and the assigned group of the participant will be determined.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Organizational Committee of Ethics in Biomedical Research

Street address

Tehran - Shahid Chamran Highway-Yemen Street - Shahid Arabi Street next to Ayatollah Taleghani Hospital

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-12-04, 1401/09/13

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.578

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

azoospermia

ICD-10 code

N46.0

ICD-10 code description

Azoospermia

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

Sperm count

Timepoint

The first sample is taken before the start of the intervention, the second sample is taken after the last session of the intervention, and the third sample is taken three months after the last intervention.

Method of measurement

sperm analysis

2

Description

Sperm morphology

Timepoint

The first sample is taken before the start of the intervention, the second sample is taken after the last session of the intervention, and the third sample is taken three months after the last intervention.

Method of measurement

sperm analysis

3

Description

Sperm motility

Timepoint

The first sample is taken before the start of the intervention, the second sample is taken after the last session of the intervention, and the third sample is taken three months after the last intervention.

Method of measurement

sperm analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: PRP is injected into the testicle, and they receive laser acupuncture twice a week for 4 consecutive weeks.

Category

Treatment - Devices

2

Description

Intervention group: PRP is injected into the testicle

Category

Treatment - Devices

3

Description

Control group: without treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohaha- Tajrish Hospital

Full name of responsible person

Mohammadhasan Mazloomfard

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Shardari st, Tajrish sq

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1989934148

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laser.cntr@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin zarghi

Street address

Yaman st, Danshjoo Blvd, Velenjak st

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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

Laser Application Research Center in Medical Sciences

Full name of responsible person

Mohammad Reza Razzaghi

Position

Professor of Urology, Shahid Beheshti University of

Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Professor of Shahid Beheshti University of Medical
Sciences

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Specialist

Other areas of specialty/work

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Person responsible for updating data

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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