

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluate the effect of platelet-rich plasma (PRP) by testicular injection on spermogram parameters of infertile men with severe oligoasthenoteratozoospermia (OAT)

Protocol summary

Study aim

Determination and comparison of DNA breakage index in infertile men before and after intervention in two groups
Determination and comparison of sperm count and motility in infertile men before and after intervention in two groups

Design

Clinical trial with a control group, single-blind, randomized, 88 patients. The random function of Excel software was used for randomization.

Settings and conduct

A Clinical trial with a control group, single-blind, randomized, in the infertility clinic of Fatemeh Hospital in Hamedan, in 2023. The patients with inclusion criteria divided into control and intervention groups with randomized block method. The patients were blinded

Participants/Inclusion and exclusion criteria

Entry criteria: age range 20-45 years, sperm count <20 million, Movement < 5*10⁶ml, progressive movement < 20%, normal morphology < 10%
Non-entry criteria: receiving other treatments and suffering from underlying diseases (such as diabetes, kidney disease, liver disease, drug and alcohol use) and types of cancer and receiving chemotherapy treatments

Intervention groups

For the intervention group, 2 cc of platelet-rich plasma is injected into the testicles by the same urologist with local anesthesia, and after three months, sperm analysis and DNA breakage index are checked, and the control group does not receive any intervention.

Main outcome variables

Sperm analysis, sperm DNA fragmentation index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220317054318N2**

Registration date: **2023-02-08, 1401/11/19**

Registration timing: **prospective**

Last update: **2023-02-08, 1401/11/19**

Update count: **0**

Registration date

2023-02-08, 1401/11/19

Registrant information

Name

Shamim Pilevari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3827 7012

Email address

sh.pilevar@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the effect of platelet-rich plasma (PRP) by testicular injection on spermogram parameters of

infertile men with sever oligoasthenoteratozoospermia (OAT)

Public title

Investigating the effect of PRP in oligospermia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 20-45 years. sperm count less than 20 million, Movement less than 106 x 5 ml, progressive movement < 20%, normal morphology < 10%

Exclusion criteria:

Receiving other treatments for oligospermia such as hormone therapy Suffering from underlying diseases (such as diabetes, kidney disease, liver disease, drug and alcohol addiction) and types of cancer and receiving chemotherapy treatments

Age

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

Gender

Male

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

In the first stage, the selection of those eligible to enter the study is done in an easy and accessible way, but after the selection of those eligible to enter the study, the participants are randomly divided into two intervention and control groups. Randomization is done by block method. In this way, we prepare 18 sheets of paper and write the letter A on 9 sheets and the letter B on the other 9 sheets. In the study, one of the sheets is taken out randomly and according to whether it is group A or B, it is assigned to the intervention and control group, and the sheets drawn out do not return to the drawer until all 18 sheets have been drawn, and after completion 18 sheets are returned to the drawer and the above operation is repeated until the number of samples is complete

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the people participating in the study are kept blind and do not obey the treatment process

Placebo

Not used

Assignment

Parallel

Other design features

The study has two intervention groups and a control group, the intervention group receives platelet-rich plasma and the control group receives placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Pasdaran street

City

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Hamadan

Postal code

6517789971

Approval date

2023-01-28, 1401/11/08

Ethics committee reference number

IR.UMSHA.REC.1401.941

Health conditions studied

1

Description of health condition studied

Oligostenoteratozoospermia

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Sperm count and motility in men

Timepoint

3 months after intratesticular platelet rich plasma injection

Method of measurement

Sperm analysis, DNA fragmentation index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:including 44 patients who were injected with 2cc of platelet-rich plasma by the urologist inside their testicles

Category

Treatment - Surgery

2

Description

Control group:44 patients who do not undergo any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemiyah Hospital

Full name of responsible person

SHamim Pilehvary

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

SHamim Pilehvary

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Subspecialist

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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