

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluate the effect of platelet-rich plasma (PRP) by testicular injection on sperm DNA fragmentation index of infertile men with severe oligoasthenoteratozoospermia (OAT)

Protocol summary

Study aim

Determining the effect of platelet-rich plasma (PRP) by testicular injection on sperm DNA fragmentation index of infertile men with severe oligoasthenoteratozoospermia (OAT)

Design

The clinical trial work has two control groups and a single-blind intervention, which is randomly allocated in a block and includes 160 samples, which are divided into two groups of 80 people.

Settings and conduct

The current study is a randomized clinical trial that is conducted in the infertility clinic of Fatemiyeh Hospital in Hamadan in 1402 on infertile men who are candidates for infertility treatment with oligoasthenoteratozoospermia. The subjects included two groups that were randomly assigned in a block manner, the control group received routine treatment, and the intervention group received platelet-rich plasma injection in the testicles. In this study, the participants are unaware of the allocation group and are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 20-45 years, sperm count < 20 million, Movement < 106 x 5 ml, progressive movement < 20%, normal morphology < 10%. Not Inclusion criteria: receiving other treatments such as hormone therapy, suffering from underlying diseases (such as diabetes, kidney disease, liver disease and alcohol addiction) and types of cancer and receiving chemotherapy treatments, signs of infection in semen, varicocele

Intervention groups

The intervention group includes study subjects who receive intratesticular injection of platelet-rich plasma. The control group includes people who only receive routine treatments.

Main outcome variables

Sperm DNA fragmentation index

General information

Reason for update

Acronym

PRP

IRCT registration information

IRCT registration number: **IRCT20220317054318N4**

Registration date: **2023-07-05, 1402/04/14**

Registration timing: **prospective**

Last update: **2023-07-05, 1402/04/14**

Update count: **0**

Registration date

2023-07-05, 1402/04/14

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

2023-07-23, 1402/05/01

Expected recruitment end date

2024-07-22, 1403/05/01

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 sperm DNA fragmentation index of infertile men with severe oligoasthenoteratozoospermia (OAT)

Public title
The effect of prp on oligospermia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age range 20-45 years Sperm count <20 million Movement less than 106 x 5 ml, progressive movement < 20%, normal morphology < 10% Not receiving other treatments such as hormone therapy Not suffering from underlying diseases (such as diabetes, kidney disease, liver disease, drug and alcohol addiction) and types of cancer and receiving chemotherapy treatments Absence of signs of infection in semen Untreated varicocele
Exclusion criteria:
Unwillingness to continue participating in the study

Age
From **25 years** old to **45 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by block method. We prepare 18 sheets of paper and write A on 9 sheets and B on other 9 sheets and put them in the drawer of the table and then each person with Inclusion criteria, one of the sheets will be given to the person randomly. Allocated and assigned to the intervention and control groups based on the letter A or B.

Blinding (investigator's opinion)
Single blinded

Blinding description
People participating in the study are unaware of the assigned group

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Fatemieh Hospital, Pasdaran St.

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۶۷۸

Approval date

2023-06-10, 1402/03/20

Ethics committee reference number

IR.UMSHA.REC.1402.227

Health conditions studied

1

Description of health condition studied

Oligostenoteratozoospermia

ICD-10 code

N46.1

ICD-10 code description

Oligospermia

Primary outcomes

1

Description

Sperm DNA fragmentation index

Timepoint

Before the start of the intervention and after 3 months from the time of PRP injection

Method of measurement

Sperm DNA breakage index test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes sample subjects receiving platelet-rich plasma via intratesticular injection

Category

Treatment - Other

2

Description

Control group: Sample subjects receiving routine

treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemieh hospital
Full name of responsible person
Shamim pilehvari
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Pasdaran street
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Sh.pilehvari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Reza shokohi
Street address
Shahid Fahmede Boulevard
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Fanavari@umsha.ac.ir
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 pilehvari
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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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