

# 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\*10<sup>6</sup>ml, 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

Hamedan

##### Province

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

##### Street address

Pasdaran Street

##### City

Hamedan

##### Province

Hamadan

##### Postal code

6517789971

##### Phone

+98 81 3834 0266

##### Email

sh.pilevar@umsha.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Reza SHokohi

##### Street address

Pasdaran Street

##### City

Hamedan

##### Province

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##### Postal code

6517789971

##### Phone

+98 81 3838 0749

##### Email

Sh.pilevar@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 Pilehvary

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Gynecology and Obstetrics

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

SHamim Pilehvary

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Associate Professor

#### Latest degree

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#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

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Hamedan University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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faezehbehnam7@yahoo.com

## 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