

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 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  
**Street address**  
Pasdaran street  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
۶۵۱۷۸۳۸۶۷۸  
**Phone**  
+98 81 3131 4058  
**Email**  
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  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
۶۵۱۷۸۳۸۶۷۸  
**Phone**  
+98 81 3131 4058  
**Email**  
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  
**Street address**  
Pasdaran Street  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
۶۵۱۷۸۳۸۶۷۸  
**Phone**  
+98 81 3131 4058  
**Email**  
Sh.pilehvari@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Shamim pilehvari  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
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۶۵۱۷۸۳۸۶۷۸  
**Phone**  
+98 81 3131 4058  
**Email**  
sh.pilehvari@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences

**Full name of responsible person**

Shamim pilehvari

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Pasdaran Street

**City**

Hamedan

**Province**

Hamadan

**Postal code**

۶۵۱۷۸۳۸۶۷۸

**Phone**

+98 81 3131 4058

**Email**

sh.pilehvari@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