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 Non-obstructive Azoospermia candidate for TESE

Protocol summary

Study aim

Determining and comparing the effect of platelet-rich plasma by testicular injection on the number, motility, and morphology of sperm in infertile men with non-obstructive ezoospermia candidates for TESE before and after the intervention in two groups

Design

Blocked randomized clinical trial with control group; a blind man; Block randomized; 68 patients.

Settings and conduct

The research environment is the infertility clinic of Fatemieh Hospital in Hamedan and the time of the research is in 1401-1402. The research population includes all infertile men who are candidates for infertility treatment with non-obstructive azoospermia referring to the infertility clinic of Fatemieh Hospital. The research sample is any infertile man suffering from non-obstructive azoospermia, referring to the infertility clinic of Fatemieh Hospital in Hamadan. For the intervention group, PRP 2CC is injected into the testicle tissue by the same urologist under local anesthesia, and analyzed after three months. Sperm is checked. There is no intervention for the control group.

Participants/Inclusion and exclusion criteria

Entry criteria: age range 20-45 years; lack of sperm in 2 sperm analysis samples; Non-entry criteria: receiving other treatments such as hormone therapy 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, PRP 2CC is injected into the testicle tissue by the same urologist under local anesthesia, and sperm analysis is checked after three months. There is no intervention for the control group.

Main outcome variables

Azoospermia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220317054318N3**
Registration date: **2023-02-09, 1401/11/20**
Registration timing: **prospective**

Last update: **2023-02-09, 1401/11/20**
Update count: **0**

Registration date

2023-02-09, 1401/11/20

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 Non-obstructive Azoospermia candidate for TESE

Public title
The effect of PRP in the treatment of ezoospermia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range 20-45 years Having no sperm in 2 sperm analysis samples
Exclusion criteria:
Receive other treatments Suffering from underlying diseases (such as diabetes, kidney disease, liver disease, drug and alcohol use) and types of cancer and receiving chemotherapy treatments Addiction and use of cigarettes
Age
From **20 years** old to **45 years** old
Gender
Male

Phase
0
Groups that have been masked

- Participant

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
The first stage of selection of those eligible to enter the study is done in an easy and accessible way, but after selecting those eligible to enter the study, the participants are randomly divided into two intervention and control groups. Randomization is done by block method and considering that we have two groups, blocks of 4 are used. Blocked randomization is for the purpose of making sure that exactly the same number of participants enter the 2 control intervention groups in consecutive but equal time intervals. For this purpose, random block is used. 18 sheets of paper are prepared and the letter A is written on 9 sheets and the letter B is written on the other 9 sheets. and upon the application of each eligible person to enter the study, one of the sheets is randomly drawn and assigned to the intervention and control group based on whether it is group A or B, and the drawn sheets until all 18 sheets If it has not been pulled out, it will not be returned to the drawer, and after randomly pulling out all 18 sheets, all the sheets are returned to the drawer and the above procedure is continued on the next 18 patients up to 4 times, i.e. completing the sample volume to 68
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants are blinded to the treatment method during the study.
Placebo
Not used
Assignment
Other
Other design features

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
Azoospermia
ICD-10 code
N46
ICD-10 code description
Male infertility

Primary outcomes

1

Description
Number, movement and shape of sperm
Timepoint
3 month
Method of measurement
Sperm analysis

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:34 patients who were once injected

with 2 cc of platelet-rich plasma inside the testicular tissue by a regular urologist.

Category
Treatment - Surgery

2

Description
Control group: 34 patients for whom placebo is used.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemiyah Hospital

Full name of responsible person
SHamim Pilehvary

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Pasdaran Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Reza SHokohi

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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

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Gynecology and Obstetrics

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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