Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 2026

Comparing the Effectiveness of PRP on Impotence in men 40 to 70 years old

Protocol summary

Study aim
Investigating the effect of PRP on impotence

Design
The sampling method will be random. And the participants in the present study will be divided into two intervention and control groups by tossing a coin. Phase 3

Settings and conduct
In both groups, 10 cc of blood will be taken from the patients. Then the sample will be placed in a special centrifuge. Within minutes, the PRP portion of the blood will be ready for injection in a syringe. PRP preparation and placebo injection will be done in a separate room. Samples from patients randomized to placebo will be excluded. A total of 5 ml will be injected into each corpus cavernous. In the control group, 10 cc of normal saline will be injected in the same way. The questionnaires will be completed by the subjects in the presence of the psychologist.The scores related to the International Index of Erectile Function test in two groups will be checked 3, 1 and 6 months after the injection.

Participants/Inclusion and exclusion criteria
Inclusion criteria: men aged 40 to 70 years old; use of any phosphodiesterase type 5 inhibitor (PDE5i) within one month prior to screening; presence of mild or moderate erectile dysfunction after discontinuation of PDE5i or any other erectile dysfunction treatment; agree to have sexual intercourse at least four times a month during the study period; without being under the influence

Intervention groups
In the intervention group, 5 cc will be injected into each corpus, and in The control group will also be injected with 5 cc of distilled water in each corpus.

Main outcome variables
By determining the effect of PRP in improving sexual activity in men, this product can be widely used in the treatment of erectile dysfunction.

General information

Reason for update

Acronym
Platelet-Rich Plasma

IRCT registration information
IRCT registration number: **IRCT20230609058433N1**
Registration date: **2023-07-17, 1402/04/26**
Registration timing: **prospective**

Last update: **2023-07-17, 1402/04/26**
Update count: **0**

Registration date
2023-07-17, 1402/04/26

Registrant information

Name
Amir Hossein Eslami

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the Effectiveness of PRP on Impotence in men 40 to 70 years old

Public title
The effect of PRP on impotence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men aged 40 to 70 years old Use of any phosphodiesterase type 5 inhibitor (PDE5i) within one month prior to screening Presence of mild or moderate erectile dysfunction after discontinuation of PDE5i or any other erectile dysfunction treatment Agree to have sexual intercourse at least four times a month during the study period Without being under the influence of alcohol or drugs
Exclusion criteria:
Previous major pelvic surgery or trauma Previous penile surgery or radiation therapy History of priapism, penile fracture, Peyronie's disease, penile curvature or any other anatomical disorder affecting erectile function Abnormal morning (less than 300 ng/dL or more than 1197 ng/dL) serum testosterone levels Erectile dysfunction A history of any severe medical or psychiatric illness that would interfere with participation in the study
Age
From **40 years** old to **70 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The people participating in the current study will be divided into two intervention and control groups by tossing a coin. This method is usually used to create a random sequence in two-group experiments in such a way that one of the study groups is called the lion and the group others are considered as lines and based on the desired sample volume, the same number A coin is tossed and people are randomly assigned to two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
A briefing session will be held for the psychiatrist, doctor and psychologist colleagues and they will be taught how to complete the questionnaires and the same visit. It should be mentioned that the study will be conducted in a double-blind manner and none of the colleagues will know about the main drug and the placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Arabi st., Daneshjoo boulvard, Velenjak
City
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Province
Tehran
Postal code
1983969411
Approval date
2023-06-03, 1402/03/13
Ethics committee reference number
IR.SBMU.MSP.REC.1402.077

Health conditions studied

1

Description of health condition studied
Impotence
ICD-10 code
F52.21
ICD-10 code description
Male erectile disorder

Primary outcomes

1

Description
International Index of Erectile Function(IIEF) score in the IIEF questionnaire
Timepoint
It will be checked 3, 1 and 6 months after the injection.
Method of measurement
International Index of Erectile Function, which evaluates men's erectile performance in 5 areas with 15 questions.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In both groups, 10 cc of blood will be taken from the patients. Then the sample will be placed in a special centrifuge. Within minutes, the PRP portion of the blood, containing platelets, cytokines, and growth factors, will be ready for injection in a syringe. PRP preparation and placebo injection will be done in a separate room. Samples from patients randomized to placebo will be discarded, and samples from patients randomized to PRP will be processed by an FDA-approved autologous platelet separator (Magellan Autologous Platelet Separator; Arteriocyte Medical Systems, Hopkinton, MA) to yield approximately 10 mL of PRP. Specifically, PRP is automatically separated from anticoagulated whole blood in about 15 minutes and dispensed into a separate sterile syringe. After preparing the injection, patients will be placed in a supine position and a loop will be tied around the base of the penis. A total of 5 ml will be injected into each corpus cavernous. The injection will be done within 2 minutes to minimize platelet cell damage. The entire procedure will be performed under sterile conditions without anesthesia. After administration, additional compression of the penis will be done with a bandage around the penis. The tourniquet of the penis will be removed 20 minutes after the injection and the patients will be discharged. All patients will be instructed to remove the pressure bandage at home 4 hours after injection

Category
Treatment - Other

2

Description
Control group: In the control group, 10 cc of normal saline will be injected in the same way

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada - e - tajrish hospital

Full name of responsible person
Amir Hossein Eslami

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shohada-e-tajrish hospital , shahrdari st , tajrish square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Amir Hossein Eslami

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Urology

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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