Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The Efficacy of Autologous Testicular Platelet Rich Plasma (PRP) for Patients with a History of Microdissection Testicular Sperm Extraction (mTESE) Failure: Clinical Trial

Protocol summary

Study aim

Determining the safety and effect of PRP on the process of spermatogenesis in azoospermic patients

Design

Clinical trial without control group, before and after, without blinding, randomized, on 20 patients

Settings and conduct

This study will be conducted only on 20 NOA patients referred to Royan Institute with negative mTESE history. There is no control group and blinding will not be done. After receiving the permission of the ethics committee for the research, the research samples will be selected based on the study entry criteria. After obtaining informed consent to participate in the research, they will be subjected to intratesticular PRP injection.

Participants/Inclusion and exclusion criteria

Men over 18 years with a history of non-obstructive azoospermia and at least one failed mTESE will be included in the study.

Intervention groups

After receiving the permission of the ethics committee in the research, the research samples after obtaining informed consent to participate in the research, they will be subjected to intratesticular PRP injection. To prepare PRP, the α-PRP - Celltech Biogenesis, Iran will be used.

Main outcome variables

Comparing the effect of PRP on LH hormone levels after PRP injection Comparing the effect of PRP on FSH and testosterone levels after PRP injection Comparison of the effect of PRP on individual Semen Analysis after PRP injection Comparison of the effect of PRP on the outcome of mTESE, after PRP injection Determination of fertilization rate, clinical pregnancy (hCG positive), stable implantation (more than 8 weeks) if sperm is found

General information

Reason for update

Dear IRCT Administrator, We need to update our trial record because recruitment and the trial have now ended, with final dates recorded on 2025-10-13, 1404/07/21 for recruitment and 2026-02-19, 1404/11/30 for the trial, and because the originally specified kit type was replaced in this study (from alpha PPR kit to BD) to maintain assay consistency; the previous kit data should be superseded for accurate documentation. Thank you for your support.

Acronym

IRCT registration information

IRCT registration number: **IRCT20221128056644N1**
Registration date: **2023-06-03, 1402/03/13**
Registration timing: **prospective**

Last update: **2026-05-11, 1405/02/21**
Update count: **3**

Registration date

2023-06-03, 1402/03/13

Registrant information

Name

Marjan Sabbaghian

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2730

Email address

Marjan.sabbaghian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01
Expected recruitment end date
2025-03-21, 1404/01/01
Actual recruitment start date
2024-06-16, 1403/03/27
Actual recruitment end date
2025-10-13, 1404/07/21
Trial completion date
2026-02-19, 1404/11/30

Scientific title
The Efficacy of Autologous Testicular Platelet Rich Plasma (PRP) for Patients with a History of Microdissection Testicular Sperm Extraction (mTESE) Failure: Clinical Trial

Public title
The Efficacy of testicular PRP for patients with history of mTESE failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men over 18 years Men with a history of non-obstructive azoospermia and at least one failed mTESE Spouses without any disease related to female infertility
Exclusion criteria:
Obstructive azoospermia patients Patients with systemic medical problems Patients with chromosomal disorders
Age
From **18 years** old
Gender
Male

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **20**
Actual sample size reached: **15**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Royan Institute-Academic Center for Education, Culture and Research
Street address
No. 12, Royan Alley., Hafez St., Banihashem St., Qasem Soleimani Expressway (Resalat Ave)
City
Tehran
Province
Tehran
Postal code
1665659911
Approval date
2023-05-09, 1402/02/19
Ethics committee reference number
IR.ACECR.ROYAN.REC.1402.016

Health conditions studied

1

Description of health condition studied
Non-obstructive azoospermia
ICD-10 code
N46.029
ICD-10 code description
Azoospermia due to other extratesticular causes

Primary outcomes

1

Description
Spermatogenesis in non-obstructive azoospermia patients
Timepoint
Semen Analysis before PRP injection and ≥3 months after PRP injection.
Method of measurement
Semen Analysis and Microdissection Testicular Sperm Extraction

Secondary outcomes

1

Description
Determination of fertilization rate
Timepoint
After PRP injection
Method of measurement
Microscopic observations

Intervention groups

1

Description
Intervention group: Patients with non-obstructive azoospermia have at least one mTESE failure history. After receiving the permission of the ethics committee in

the research, the research samples are selected based on the criteria for entering the study. After obtaining informed consent to participate in the research, they will be subjected to intratesticular injection of PRP. The PRP kit (BD Vacutainer® Specialty Tubes, SKU:364606) will be used to prepare PRP. The duration of PRP preparation will be less than 45 minutes. Prepared PRP is injected into the spermatic cord or the interstitial space using a 5 mL syringe. In the third month after testicular PRP, gonadotropin stimulation in the patient's wife begins on days 2 to 4 of the menstrual cycle. Sperm extraction with the mTESE method will be performed at the same time as the egg retrieval day to use fresh sperm cells. In the first stage, 3 months after PRP injection into the testicles, sperm analysis will be checked in patients. The second stage will be 6 months after the injection. According to the obtained results, the sperm is injected into the cytoplasm of the egg by assisted reproductive techniques (ICSI) and fertilization takes place.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Royan Institute

Full name of responsible person
Dr Mohammad Ali Sedighi Gilani

Street address
Royan Alley., Hafez St., Banihashem St., Qasem Soleimani Expressway (Resalat Ave)., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1665659911

Phone
+98 21 2356 2000

Email
info@royaninstitute.org

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Royan Institute

Full name of responsible person
Mohammad Ali Sadighi Gilani

Street address
Royan Alley., Hafez St., Banihashem St., Qasem Soleimani Expressway (Resalat Ave)., Tehran

City
Tehran

Province
Tehran

Postal code
1665659911

Phone
+98 21 2356 2000

Email
masadighi@gmail.com

Grant name
Royan Lotus Charity Found

Grant code / Reference number
NA

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Royan Institute

Proportion provided by this source
75

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

2

Sponsor

Name of organization / entity
Royan Institute

Full name of responsible person
Mohhamad Ali Sedighi Gilani

Street address
Royan Alley., Hafez St., Banihashem St., Qasem Soleimani Expressway (Resalat Ave)., Tehran

City
Tehran

Province
Tehran

Postal code
1665659911

Phone
+98 21 2356 2000

Email
masadighi@gmail.com

Grant name
Royan Institute for Reproductive Biomedicine Fundation

Grant code / Reference number
NA

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Royan Institute

Proportion provided by this source
25

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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Royan Institute
Full name of responsible person
Marjan Sabbaghian
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Royan Alley., Hafez St., Banihashem St., Qasem Soleimani Expressway (Resalat Ave)., Tehran
City
Tehran
Province
Tehran
Postal code
1665659911
Phone
+98 21 2356 2000
Email
marjan.sabbaghian@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Royan Institute
Full name of responsible person
Marjan Sabbaghian
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Royan Alley., Hafez St., Banihashem St., Qasem Soleimani Expressway (Resalat Ave)., Tehran
City
Tehran
Province
Tehran
Postal code
1665659911
Phone
+98 21 2356 2000
Email
marjan.sabbaghian@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Royan Institute
Full name of responsible person
Dr Marjan Sabbaghian
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Royan Alley., Hafez St., Banihashem St., Qasem Soleimani Expressway (Resalat Ave)., Tehran
City
Tehran
Province
Tehran
Postal code
1665659911
Phone
+98 21 2356 2000
Email
marjan.sabbaghian@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not 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