

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was replaced in this study (from alpha PPR kit to BD) to maintain assay consistency; the previous kit data should be superseded for accurate documentation.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

Mohammad 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

Phone
+98 21 2356 2000
Email
marjan.sabbaghian@gmail.com

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

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