

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### investigation of the effect of Plasma Rich Growth Factor (PRGF) in treatment of patient with azoospermia

#### Protocol summary

##### Study aim

Investigation of plasma rich growth factor in treatment of patients with azoospermia

##### Design

Clinical trial without control group, community based, not blinded, Non-randomised controlled study

##### Settings and conduct

This study will be done in najmeyeh infertility center and kerman medical university. After selection of patients by clinician, their blood will be taken and PRGF provided. Then PRGF for every 2 weeks were injected for 3 times. and the patients will be follow up for 3 and 6 months after injection.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients with non obstructive azoospermia 2- Signs of maturation arrest in testis biopsy 3- Patients aged between 20-65 years Exclusion criteria: 1- patients with obstructive azoospermia 2- Patients with previous testis surgery 3- Males with genital tract infection or anatomical abnormalities 4- Patients with severe medical problems 5- chromosomal abnormalities 6- presence of Sertoli cell only syndrome in testis biopsy

##### Intervention groups

Plasma rich in growth factors prepared from the patient's blood is injected three times at intervals of every 2 weeks to the patient's testicles and after 3 months and 6 months from the last injection, the effect of this extract on the spermatogenesis of the patients will be measured.

##### Main outcome variables

Investigation or increase in sperms in spermatogram  
Investigation in improvement in spermatogenesis in biopsy  
Increased in possibility of fertility

#### General information

##### Reason for update

##### Acronym

TAP

#### IRCT registration information

IRCT registration number: **IRCT20140911019125N2**

Registration date: **2019-02-21, 1397/12/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-02-21, 1397/12/02**

Update count: **0**

#### Registration date

2019-02-21, 1397/12/02

#### Registrant information

##### Name

**Name of organization / entity**

##### Country

Iran (Islamic Republic of)

##### Phone

+98 32 24618

##### Email address

afarsinejad@kmu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-02-20, 1397/12/01

#### Expected recruitment end date

2020-02-20, 1398/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

investigation of the effect of Plasma Rich Growth Factor (PRGF) in treatment of patient with azoospermia

#### Public title

Treatment of azoospermia with plasma rich growth

factors

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patient with non-obstructive azoospermia Signs of maturation arrest in testis biopsy patients aged between 20-65 years

### Exclusion criteria:

Patients with obstructive azoospermia Patients with pervious testis surgery Males with genital tract infection or anatomical abnormalities Patients with severe medical problems Chromosomal abnormality Present of Sertoli cell only syndrome in biopsy of testis

## Age

From **20 years** old to **65 years** old

## Gender

Male

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **27**

## 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

Ethics committee of kerman university of medical science

##### Street address

Haft Bagh Blvd, Kerman university of medical science

##### City

kerman

##### Province

Kerman

##### Postal code

7616911333

#### Approval date

2018-12-10, 1397/09/19

#### Ethics committee reference number

IR.KMU.REC.1397.360

## Health conditions studied

### 1

#### Description of health condition studied

Infertility treatment

#### ICD-10 code

N50.8

#### ICD-10 code description

Other specified disorders of male genital organs

## Primary outcomes

### 1

#### Description

Investigation and increasing in sperms in spermogram

#### Timepoint

Before intervention and 3, 6 months after intervention

#### Method of measurement

Microscopic measurement

### 2

#### Description

Investigation and improvement in spermatogenesis in biopsy

#### Timepoint

Before intervention and 3 , 6 months after intervention

#### Method of measurement

Microscopic measurement

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In this study, own of the patient's blood derivatives (Platelet rich growth factors/PRGF) is used. This product is injected 3 times at intervals of 2 weeks to patients.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Najmiyeh infertility center

##### Full name of responsible person

Mohsen Karvar

##### Street address

Haft Bagh Blvd, Najmiyeh infertility Center

##### City

Kerman

##### Province

Kerman

**Postal code**  
7613657761  
**Phone**  
+98 34 3323 3410  
**Email**  
Mohsenkarvar@yahoo.com

**City**  
kerman  
**Province**  
Kerman  
**Postal code**  
7616911333  
**Phone**  
+98 34 3132 5374  
**Email**  
afarsinejad@kmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Abbas Pardakhty  
**Street address**  
Haft bagh Blvd. kerman university of medical science  
**City**  
kerman  
**Province**  
Kerman  
**Postal code**  
7616911333  
**Phone**  
+98 34 3226 3855  
**Email**  
abpardakhty@kmu.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Kerman 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**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Alireza Farsinejad  
**Position**  
assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Hematology  
**Street address**  
Haft bagh Blvd, kerman university of medical science

#### Person responsible for scientific inquiries

##### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Alireza Farsinejad  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Hematology  
**Street address**  
Haft Bagh Blvd, kerman university of medical science  
**City**  
kerman  
**Province**  
Kerman  
**Postal code**  
7616911333  
**Phone**  
+98 34 3132 5374  
**Email**  
afarsinejad@kmu.ac.ir

#### Person responsible for updating data

##### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Alireza Farsinejad  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Hematology  
**Street address**  
Haft-Bagh Blvd, kerman university of medical science  
**City**  
kerman  
**Province**  
Kerman  
**Postal code**  
7616911333  
**Phone**  
+98 34 3132 5374  
**Email**

## 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 additional data

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

In our study non of the personal data of patients will be shared. Only data that are related to outcomes of intervention will be shared.

### When the data will become available and for how long

starting 6 months after publication

### To whom data/document is available

The data will be available for people working in academic institutions and clinicians.

### Under which criteria data/document could be used

Applicants are only allowed to use received data in clinical and they are not allowed to published them.

### From where data/document is obtainable

1- Phone: 034-31325374 2- e-mail:

afarsinejad@kmu.ac.ir 3- Fax: 034-31325375 4- address:

Haft bagh Blvd, Kerman university of medical science Dr.

Alireza Farsinejad

### What processes are involved for a request to access data/document

Applicant can receive information after contact and send e-mail up to 10 days.

### Comments