Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 measurment

2

Description

Investigation and improvement in spermatogenesis in biopsy

Timepoint

Before intervention and 3 , 6 months after intervention

Method of measurement

Microscopic measurment

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

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

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

afarsinejad@kmu.ac.ir

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