

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of efficacy of subendometrial PRP injection for FET cycle of RIF patients

Protocol summary

Study aim

Evaluation the efficacy of subendometrial PRP injection on implantation

Design

Randomized double blind clinical trial, with 30 patients who are allocated in each parallel group, This is phase 3 trial that patient and physician (who is different from surgeon that perform procedure) will evaluate the outcome will be blinded regarding groups.

Settings and conduct

This randomized blinded clinical trial will be conducted in case(hysteroscopy crushing endometrium, PRP) and control (hysteroscopy crushing endometrium) groups at IVF clinic of YAS hospital.

Participants/Inclusion and exclusion criteria

History of recurrent implantation failure Having good quality embryo No uterine anomaly

Intervention groups

For 30 patients with history of recurrent implantation failure will be included in the randomized blinded clinical trial for PRP injection to four points at anterior and posterior and lateral wall of subendometrial uterine cavity during luteal phase hysteroscopy and crushing endometrium.

Main outcome variables

Chemical pregnancy, clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002576N29**

Registration date: **2023-08-10, 1402/05/19**

Registration timing: **prospective**

Last update: **2023-08-10, 1402/05/19**

Update count: **0**

Registration date

2023-08-10, 1402/05/19

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8831 3955

Email address

fdavaritanha@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2025-03-05, 1403/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of subendometrial PRP injection for FET cycle of RIF patients

Public title

Efficacy of subendometrial PRP injection for FET cycle of RIF patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

RIF patients Have good quality embryo Having signed

informed consent Age 20-40 years Exclusion criteria: Severe male infertility BMI>30 Uncontrolled hypothyroidism User of corticosteroids User of glucose control agents CNS tumour Uterine malformation Cavity distorting lesions Severe endometriosis Liver disease Asherman syndrome Age From 20 years old to 40 years old Gender Female Phase 2-3 Groups that have been masked • Participant • Care provider Sample size Target sample size: 60 Randomization (investigator's opinion) Randomized Randomization description Randomization rule: First 30 letters A and 30 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patients. In addition, interventions A (case group : hysteroscopycrushingendometrium, subendometrial PRP injection) or B (control group: hysteroscopy crushing endometrium) are determined by a lot. Blinding (investigator's opinion) Double blinded Blinding description Patient and physician (she in not the same person that perform procedure)who evaluate the outcome are blinded regarding control(hysteroscopy crushing endometrium) or case (hysteroscopy crushing endometrium, PRP) groups. Placebo Not used Assignment Parallel Other design features	Tehran University medical sciences, Ghods Avenue, Keshavarz Blvd City Tehran Province Tehran Postal code 15978 Approval date 2023-06-23, 1402/04/02 Ethics committee reference number IR.TUMS.MEDICINE.REC.1402.200
Secondary Ids empty	Health conditions studied
Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Tehran University of medical sciences Street address Fatemeh Saeidi, sixth floor of central building of	<u>1</u> Description of health condition studied Infertility ICD-10 code Female inf ICD-10 code description N97.8 Primary outcomes <u>1</u> Description Endometrial thickness Timepoint At the day of start progesterone Method of measurement Transvaginal sonogram <u>2</u> Description Chemical pregnancy Timepoint Two weeks after embryo transfer Method of measurement Bhcg titer Secondary outcomes <u>1</u> Description Clinical pregnancy Timepoint Cardiac activity four weeks after embryo transfer Method of measurement Transvaginal sonogram Intervention groups <u>1</u> Description "Intervention group": At the time of hysteroscopy in

luteal phase under anesthesia, RPP that will be prepared before surgery, injected in subendometrial area of endometrial cavity at four points with needle.

Category

Treatment - Surgery

2

Description

"Control group": At the time of surgery hysteroscopy and crushing endometrium will be performed, in luteal phase under anesthesia,

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Hospital

Full name of responsible person

Fatemeh Davari Tanha

Street address

IVF ward,Yas hospital, North Nejatollahi Avenue, Karim khan Zand Bridge, Villa Street

City

Tehran

Province

Tehran

Postal code

15978

Phone

+98 21 8880 0115

Email

Fatedavtanha@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Davari Tanha

Street address

IVf ward,Yas hospital, North Nejatollahi Avenue, Karim khan Bridge,

City

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Province

Tehran

Postal code

15978

Phone

+98 21 8880 0115

Email

Fatedavtanha@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Davari Tanha

Position

Professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Yas hospital, North Nejatollahi Avenue, Karim khan Bridge

City

Tehran

Province

Tehran

Postal code

15978

Phone

+98 21 8880 0115

Email

Fatedavtanha@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Davari Tanha

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Yas hospital, North Nejatollahi Avenue, Karim khan Zand Bridge, Villa Street

City

Tehran
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Tehran
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Phone
+98 21 8880 0115
Email
Fatedavtanha@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Davari Tanha
Position
Professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Yas hospital, North Nejatollahi Avenue, Karim khan
Zand Bridge
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Tehran
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Phone
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Email
Fatedavtanha@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

SPSS file

When the data will become available and for how long

After publishing the article

To whom data/document is available

To researchers

Under which criteria data/document could be used

Requesting by email

From where data/document is obtainable

From email fatedavtanha@gmail.com

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

Email to fatedavtanha@gmail.com

Comments