

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Study of the Effect of injecting the combination of exosomes extracted from follicular fluid, PRP & gonadotropins into the ovaries of POF & POI Patients.

Protocol summary

Study aim

Stimulation of follicular growth in patients and recovery of menstrual cycle and sex hormone levels followed by the birth of a live child Investigating the effect of exosomes with gonadotropins and PRP

Design

20 qualified patients refers to Tahoori clinic(QOM) will be selected. Medical history, general, abdominal and local examinations, clinical tests (general status using CBC, liver, kidney, thyroid and ovarian function tests by FSH, LH, E2, AMH, ultrasound and chromosomal examination to confirm karyotype) Healthy typing will be checked. Exosomes is extracted from follicular fluid by PEG method, then they will be injected together with enriched plasma (PRP) into the ovarian tissue of POF and POI patients.

Settings and conduct

This study will be conducted in Tahura Infertility Center, for this purpose 10 qualified clients of Tahura Infertility Center will be selected. All cases in terms of medical history, general, abdominal and local examinations, clinical tests (general condition using CBC, test, kidney, thyroid and ovarian function by FSH, LH, E2, AMH, ultrasound and chromosomal examination to confirm karyo) . Healthy typing will be checked.

Participants/Inclusion and exclusion criteria

Women with premature menopause POF Women with premature ovarian failure POI Normal women with Grade(A) eggs Non-entry conditions: Idiopathic infertile women

Intervention groups

This study was conducted on eight groups: 1.The first group will not receive any stimulus as a control. 2.Only exosome. 3.Only PRP. 4.only gonadotropin. 5. Exosome and PRP. 6. Exosome and gonadotropin. 7.Gonadotropin and PRP 8. Exosome, gonadotropin and PRP, they will receive.

Main outcome variables

increase ovarian reserve; proper ovarian function; The possibility of fertility of POF, POI women; recovery of menstrual cycle and sex hormone levels; Birth of a live child

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230528058312N1**

Registration date: **2023-06-07, 1402/03/17**

Registration timing: **prospective**

Last update: **2023-06-07, 1402/03/17**

Update count: **0**

Registration date

2023-06-07, 1402/03/17

Registrant information

Name

Seyed Reza Tabatabaee Qomi

Name of organization / entity

Tahoori Infertility Treatment & limited surgery Clinic

Country

Iran (Islamic Republic of)

Phone

+98 25 3725 4719

Email address

tahoori.clinic@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-05-21, 1403/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Study of the Effect of injecting the combination of exosomes extracted from follicular fluid, PRP & gonadotropins into the ovaries of POF & POI Patients.
Public title
Study of the Effect of the combination of exosomes extracted from follicular fluid, PRP & gonadotropins into the ovaries of POF & POI Patients.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women with premature menopause POF Women with premature ovarian failure POI Normal women with Grade A eggs
Exclusion criteria:
Women with idiopathic infertility Women with adequate ovarian reserve
Age
From **20 years** old to **40 years** old
Gender
Female
Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University, Qom branch

Street address

Shahzad Seyed Ali St., Islamic Azad University, Qom

branch
City
Qom
Province
Ghoum
Postal code
3747113135
Approval date
2023-04-11, 1402/01/22
Ethics committee reference number
IR.IAU.QOM.REC.1402.077

Health conditions studied

1

Description of health condition studied

Premature Ovarian failure(POF) / Premature Ovarian Insufficiency (POI)

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

Absence of eggs in the ovaries of women under 40 years and primary or secondary amenorrhea for more than 4 months in women under 40 years with an elevated serum level of Follicular Stimulated Hormone(higher than 25 mIU/mL

Timepoint

15 days after the injection and then every month at the time of ovulation during one year

Method of measurement

Transvaginal ultrasound device, Hormonal Test by Elisa Kit.

Secondary outcomes

empty

Intervention groups

1

Description

1.Intervention group: Infertile women with primary or secondary amenorrhea for more than 4 months under 40 years old with an elevated serum level of FSH (higher than 25 mIU/mL).This group only autologous PRP(plate rich plasma) will be received. PRP was prepared from 40 mL of peripheral blood by the buffy coat protocol In brief, whole blood was divided into two aliquots and centrifuged at 3,000 rpm for 8 min at room temperature to form three layers.The top platelet poor plasma and the middle layer were transferred to another two sterile tube and then centrifuged again at 4,000 rpm for 5 min. After removal of upper portion of the supernatant, each

pellet was reconstituted with 2.5 ml of supernatant. patient is lying in the dorsal lithotomy position, and a needle (Towako Trans myometrial Set 18 GAx 325 mm, Cook, Australia) with an angle of 15 to 30 degrees is advanced into ovarian stroma under vaginal ultrasound guidance (Honda 2000). Under intravenous sedation using 100 mg propofol (Fresenius Kabi Austria GmbH, Graz, Austria). No antibiotic will not be used, and the patient withstood the process without painful sensation.

Category

Treatment - Other

2

Description

2. Intervention group: Infertile women with primary or secondary amenorrhea for more than 4 months under 40 years old with an elevated serum level of FSH (higher than 25 mIU/mL). this group receive exosome (100µg/ml) from the follicular fluid of fertile women referred to Tahura infertility center for IVF due to male factor infertility, who have been examined for HIV, HCV and HPV health and have grade A eggs, will be extracted according to the protocol provided by Eswaran with the help of Andreu Polyethylene glycol (PEG) (600 kDa). In order to check the presence of exosomes with the Mestro brand nanodrop spectrophotometer, the concentration of DNA and RNA, with the ZEISS brand SEM electron microscope, the presence of exosomes will be checked. In addition, CD9, CD 63, CD81, CD82 factors will be checked with the help of Beckman brand flow cytometry. on the second and fifth day of the participants' menstrual cycle will be injected into their superficial layer of the ovary, only once during the treatment cycle. The patient is lying in the dorsal lithotomy position, and a needle (Towako Trans myometrial Set 18 GAx 325 mm, Cook, Australia) with an angle of 15 to 30 degrees is advanced into ovarian stroma under vaginal ultrasound guidance (Honda 2000). Under intravenous sedation using 100 mg propofol (Fresenius Kabi Austria GmbH, Graz, Austria). No antibiotic will be used, and the patient withstood the process without painful sensation.

Category

Treatment - Other

3

Description

3. Intervention group: Infertile women with primary or secondary amenorrhea for more than 4 months under 40 years old with an elevated serum level of FSH (higher than 25 mIU/mL) only gonadotropin, 1 ml of 150 IU of FSH/75 IU of LH (Pergoveris, Merck Serono, Aubonne, Switzerland) was slowly infused into ovarian tissue, 0.5 ml in each ovary, under intravenous sedation using 100 mg propofol (Fresenius Kabi Austria GmbH, Graz, Austria). No antibiotic is used, and the patient withstood the process without painful sensation. No visible side effect will be noted in the whole procedure.

Category

Treatment - Other

4

Description

4. Intervention group: infertile women with primary or secondary amenorrhea for more than 4 months under 40 years old with an elevated serum level of FSH (higher than 25 mIU/mL). this group receive exosome (100µg/ml) and autologous PRP (4ml), under intravenous sedation using 100 mg propofol (Fresenius Kabi Austria GmbH, Graz, Austria). No antibiotic will be used, and the patient withstood the process without painful sensation.

Category

Treatment - Other

5

Description

5. Intervention group: Infertile women with primary or secondary amenorrhea for more than 4 months under 40 years old with an elevated serum level of FSH (higher than 25 mIU/mL) will be received gonadotropin 1 (150 IU rFSH/75 IU rLH, Pergoveris, Merck Serono, Aubonne, Switzerland) and exosome (100µg/ml) extracted from Follicular fluid of fertile woman injected under intravenous sedation using 100 mg propofol (Fresenius Kabi Austria GmbH, Graz, Austria). No antibiotic is used, and the patient withstood the process without painful sensation. No visible side effect is noted in the whole procedure.

Category

Treatment - Other

6

Description

Intervention group: Infertile women with primary or secondary amenorrhea for more than 4 months under 40 years old with an elevated serum level of FSH (higher than 25 mIU/mL) receive gonadotropin 1ml (150 IU rFSH/75 IU rLH) (Pergoveris, Merck Serono, Aubonne, Switzerland) and autologous PRP (4mL) prepared by the buffy coat protocol be injected under intravenous sedation using 100 mg propofol (Fresenius Kabi Austria GmbH, Graz, Austria). No antibiotic is used, and the patient withstood the process without painful sensation.

Category

Treatment - Other

7

Description

7. Intervention group: infertile women with primary or secondary amenorrhea for more than 4 months under 40 years old with an elevated serum level of FSH (higher than 25 mIU/mL) received gonadotropin 1ml (150 IU rFSH/75 IU rLH) (Pergoveris, Merck Serono, Aubonne, Switzerland), autologous PRP (4mL) prepared by the buffy coat Porotocol and exosome (100µg/ml) extracted from Follicular fluid of fertile woman injected under intravenous sedation using 100 mg propofol (Fresenius Kabi Austria GmbH, Graz, Austria). No antibiotic is used, and the patient withstood the process

without painful sensation.

Category

Treatment - Other

8**Description**

Control group: infertile women with primary or secondary amenorrhea for more than 4 months under 40 years old with an elevated serum level of FSH (higher than 25 mIU/mL). they do not receive any stimulants.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tahoor,Specialized Infertility Treatment And limited Surgery Center

Full name of responsible person

Dr. seyed Reza Tabatabaee Qomi

Street address

Tahoor infertility treatment and limited surgery clinic,Tahoor steet, Jamkaran

City

Qom

Province

Ghoum

Postal code

3747113135

Phone

+98 912 746 0016

Email

taba_1359@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tahoor,Specialized Infertility treatment And limited surgery Center

Full name of responsible person

seyed Reza Tabatabaee Qomi

Street address

Superspecialized Infertility Treatment And surgurycenter,Tahoor street,Jamkaran,

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Email

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tahoor,Specialized Infertility treatment And limited surgery Center

Proportion provided by this source

90

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**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Tahoor infertility treatment and limited surgery clinic

Full name of responsible person

Dr.seyed Reza Tabatabaee Qomi

Position

Treatmen Manager

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

Tahoor infertility treatment and limited surgery clinic,Tahoor street,Jamkaran

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tahoor infertility treatment and limited surgery clinic

Full name of responsible person

Dr.seyed Reza Tabatabaee Qomi

Position

Treatmen Manager

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

All data is shareable after de-identifying Participants

When the data will become available and for how long

Since March 2024

To whom data/document is available

Researchers and Treatment Centers

Under which criteria data/document could be used

method and statistical analysis of the request can be used via email

From where data/document is obtainable

Through The Corresponded Email:taba_1359@yahoo.com

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

En after about a week of requesting by email, if the request can be acceptable it will be sent

Comments