Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Study of the Effect of injecting the combination of exosomes extracted from follicular flouid,PRP & gonadotropns 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 Tahoora cilinic(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

Tahoora Infertility Treatment & limited surgery Clinic

Country

Iran (Islamic Republic of)

Phone

+98 25 3725 4719

Email address

tahoora.clnic@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 flouid,PRP & gonadotropns into the ovaries of POF & POI Patients.

Public title

Study of the Effect of the combination of exosomes extracted from follicular flouid,PRP & gonadotropns 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 centrifugedat 3,000 rpm for 8 min at room temperature to form three layers.The top platelet poor plasma and the middle layerwere transferred to another two sterile tube and then centrifugedagain 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 GA× 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 Mrestro 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 GA× 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,MerckSerono, Aubonne, Switzerland) was slowly infused into ovarian tissue, 0.5 ml in each ovary, under intravenous sedationusing 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: nfertile 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 sedationusing 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(150IUrFSH/75 IU rLH, Pergoveris,MerckSerono, 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 theprocess without painful sensation. No visible side effect is notedin 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(150IUrFSH/75IU rLH) (Pergoveris,MerckSerono, Aubonne, Switzerland) andautologous PRP (4mL) prepared by 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 theprocess 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(150IUrFSH/75IU rLH) (Pergoveris,MerckSerono, Aubonne, Switzerland) ,autologous PRP (4mL) prepared by by the buffy coat Porotocole 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 theprocess

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
Tahoora,Specialized Infertility Treatment And limited Surgery Center

Full name of responsible person
Dr. seyed Reza Tabatabaee Qomi

Street address
Tahoora infertility treatment and lmited surgury clinic,Tahoora steet, Jamkarant

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
Tahoora,Specialized Infertility treatment And limited surgery Center

Full name of responsible person
seyed Reza Tabatabaee Qomi

Street address
Superspecialized Infertility Treatment And surgurycenter,Tahoora street,Jamkaran,

City
Qom

Province
Ghoum

Postal code
3747113135

Phone
+98 912 746 0016

Email
taba_1359@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Tahoora,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
Tahoora infertility treatment and lmited surgury 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
Tahoora infertility treatment and lmited surgury clinic,Tahoora street,Jamkaran

City
Qom

Province
Ghoum

Postal code
3747113135

Phone
+98 25 3725 4719

Email
taba_1359@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tahoora infertility treatment and lmited surgury 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
Tahoora infertility treatment and lmited surgury

clinic,Tahoora Street, Jamkaran

City
Qom

Province
Ghoum

Postal code
3747113135

Phone
+98 25 3725 4719

Email
taba_1359@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tahoora infertility treatment and lmited surgury 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
Tahoora infertility treatment and lmited surgury clinic,Jamkaran,Tahoora street

City
Qom

Province
Ghoum

Postal code
3747113135

Phone
+98 25 3725 4719

Email
taba_1359@yahoo.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
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