Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of exosome injection extracted from seminal plasma, stem cells derived from Wharton's testosterone gel and FSH on the process of spermatogenesis in NOA individuals.

Protocol summary

Study aim

Investigating the effect of exosome, stem cell injection along with FSH and testosterone for the differentiation of germ cells of non-obstructive Azoospermia to reach gametes that can be injected into eggs.

Design

50 patients with non-obstructive azoospermia refer to Tahura infertility treatment center were identified and after obtaining informed consent,they were included in the plan. Treatment with FSH and testosterone is combined with exosomes isolated from the seminal fluid of healthy individuals and stem cells obtained from Wharton's gel. After three months, these people are re-examined. If sex cells that can be injected into eggs are obtained, sperm and eggs are injected during the laboratory process.

Settings and conduct

50 Azoospermia people will be selected to the Tahora Clinic. These people are divided into 7 groups into the testicular tissue of the first group only exosome and the second group only the Substation and the third group only FSH and testosterone, the fourth group exosome and smelling, the fifth group of the Cell and FSH and testosterone, and the sixth group exosome and Gonadotropin and the seventh group Exosomes, sewage and FSH and testosteronewill be injected.

Participants/Inclusion and exclusion criteria

Patients with normal semen samples for exosome extraction from their semen. NOA patients who underwent diagnostic TESE. Patients with abnormal semen samples.

Intervention groups

Stem cell recipient، Exosome recipient، FSH receptor، Stem cell and exosome recipient، Stem cell and FSH recipient، Exosome and FSH receptor، Stem cell, exosome and FSH recipient، Control group, which are azoospermia individuals who do not receive anything.

Main outcome variables

Differentiation of germinal tubercle to obtain injectable germ cells; The possibility of owning a child for NOA Patient, use in infertility treatment clinics.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230528058312N2**
Registration date: **2024-02-07, 1402/11/18**
Registration timing: **prospective**

Last update: **2024-02-07, 1402/11/18**
Update count: **0**

Registration date

2024-02-07, 1402/11/18

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

2024-02-20, 1402/12/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of exosome injection extracted from seminal plasma, stem cells derived from Wharton's testosterone gel and FSH on the process of spermatogenesis in NOA individuals.

Public title
Exosome and stem cells therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People who do not have sperm in their semen samples (Azoospermia) will be selected. In order to exosome extraction from seminal plasma, people who have normal semen samples (according to global standards (WHO)) will be selected.
Exclusion criteria:
People with obstructive azoospermia Azoospermia whose testicular tissue biopsy did not show germ cells
Age
No age limit
Gender
Male

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **50**
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 (Research Ethics Committee)
Street address
Shahzad Seyed Ali St., Islamic Azad University, Qom branch
City
Ghoum
Province
Ghoum
Postal code
3747113135
Approval date
2023-11-27, 1402/09/06
Ethics committee reference number
IR.IAU.QOM.REC.1402.211

Health conditions studied

1

Description of health condition studied
Non-obstructive azoospermia
ICD-10 code
N46
ICD-10 code description
Male infertility

Primary outcomes

1

Description
Absence of sperm, observation of germ cells in testicular tissue pathology.
Timepoint
3 months after the injection of stem cells, exosome, FSH, testosterone
Method of measurement
Siemens analysis, TESE surgery

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group receives only 50 microliters of exosomes extracted from the semen of healthy people. Semen samples are collected in the Andrology Laboratory of Tahura Infertility Clinic from patients who come for semen analysis, and then normal samples that count more than 25 *106, morphology above 4%, motility above 50%, which is more than 40% progressive movement and finally their DFA is less than 15% are isolated. It should be noted that samples taken from people are examined for HIV, HCV and HPV health. and if the tests are negative, after collecting the samples, Polyethylene glycol (PEG (6000 kDa) will be prepared with a concentration of 500 mg/ml along with sterile PBS (pH 7.4) to extract the exosome. Then 50 µl of PEG and PBS solution with the mentioned concentration with 250 µl of cement liquid that passes

through the 0.22 filter, finally after incubation of the mentioned mixture for 12 hours at 4 °C, with a rotation of 3000 rpm for 30 minutes They will be centrifuged at a temperature of 4°C. The supernatant is discarded and the plate is used to check the presence of exosomes with a nanodrop spectrophotometer, the protein concentration of DNA and RNA is then checked with an electron microscope for the presence of exosomes. In addition, CD9, CD 63, CD81, CD82 It will be checked. Finally, 50 microliters of the extracted exosome will be injected into the testicles of non-obstructed azoospermia individuals with an insulin syringe.

Category

Treatment - Other

2

Description

Intervention group:This group will receive stem cells extracted from Wharton's gel. Stem cells will be prepared from 7 umbilical cord samples from the private cord blood bank. Umbilical cord donors are healthy mothers, free of genetic and underlying diseases and based on serology tests and free of viral diseases (syphilis, HTLV I/II, HBV, HCV, HIV, and CMV) will be collected during delivery and in sterile PBS containing Penicillin and streptomycin antibiotics will be sent to the umbilical cord stem cell extraction laboratory for stem cell extraction. Finally, vials with a concentration of 10 x 107 cells will be delivered. And a concentration of 5 x 107 cells is injected into each testicle.

Category

Treatment - Other

3

Description

Intervention group: Participants in this group will be given 10 micromoles of testosterone and 500IU/L of FSH hormone, and after 3 month we will check the differentiation of germ cells with the help of pathology test.

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

Islamic Azad University, Qom branch, Shahzadeh Seyed Ali St.,Qom

City

Ghoum

Province

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3747113135

Phone

+98 912 746 0016

Email

taba_1359@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research assistant for infertility treatment andTahoora limited surgery clinic

Full name of responsible person

seyed Reza Tabatabaee Qomi

Street address

Islamic Azad University, Qom branch, Shahzadeh Seyed Ali St.,Qom

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Grant name

Tahoora,Specialized Infertility treatment And limited surgery Center

Grant code / Reference number

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

Yes

Title of funding source

Research assistant for infertility treatment andTahoora limited surgery clinic

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tahoora infertility treatment and lmited surgury clinic

Full name of responsible person

seyed Reza Tabatabaee Qomi

Position

Treatmen Manager

Latest degree

Ph.D.

Other areas of specialty/work
Infertility

Street address
Tahoora infertility treatment and lmited surgury clinic,Tahoora street,Jamkaran

City
Ghoum

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Postal code
3747113135

Phone
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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
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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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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 obtained after identification of study cases can be shared.

When the data will become available and for how long
All information is accessible in April 2025

To whom data/document is available
Our data will be available for all researchers and Doctors

Under which criteria data/document could be used
All information related to the performed ultrasounds, tests related to exosome and stem cell extraction will be accessible

From where data/document is obtainable
Applicants can contact one of the following email addresses to receive documents or data: asalighe@yahoo.com taba_1359@yahoo.com

What processes are involved for a request to access data/document
Three weeks after sending the applicant's message, the requested documents and files will be sent.

Comments