Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of protective effect of seminal exosomes on the quality of Frozen-Thawed Sperms in oligoasthenoteratozoospermia men

Protocol summary

Study aim
Improving the sperm quality of oligoasthenoteratozoospermia patients after freezing-thawing with the help of the protective effect of seminal exosomes and using this method for sperm freezing in infertility treatment centers.

Design
A randomized clinical trial with control group and parallel design, double blinded, on 100 patients. Randomization will be done using sealedenvelope.com.

Settings and conduct
The location of the study is the andrology laboratory of Royan Research Institute in Tehran; The studied population: oligoasthenoteratozoospermia patients and normal people referring to Royan Clinic; Blinding and explanation of the blinding method: double-blinded in such a way that the patients and the data analyst are not aware of the sample allocation method

Participants/Inclusion and exclusion criteria
Inclusion criteria: Normozoospermia men; Oligoasthenoteratozoospermia men; age of 25 to 40 years old. Non-inclusion criteria: Smokers; varicocele; genital infections; hydrocele; endocrine diseases

Intervention groups
Control: Incubation of sperm of Normozoospermia individuals with seminal exosome of Normozoospermia individuals; Intervention group 1: Incubation of sperm of Normozoospermia individuals with seminal exosome of Oligoasthenoteratozoospermia patients; Intervention group 2: Incubation of sperm from Oligoasthenoteratozoospermia patients with seminal exosome of Normozoospermia individuals; Intervention group 3: Incubation of sperm of Oligoasthenoteratozoospermia patients with seminal exosome of Oligoasthenoteratozoospermia patients

Main outcome variables
Sperm motility and count; total antioxidant capacity (TAC); apoptosis; mitochondrial membrane potential (MMP); DNA breakage

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230207057345N1**
Registration date: **2023-05-21, 1402/02/31**
Registration timing: **prospective**

Last update: **2023-05-21, 1402/02/31**
Update count: **0**

Registration date
2023-05-21, 1402/02/31

Registrant information

Name
Saeede Rezaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4601 5487

Email address
srezaei@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2023-08-22, 1402/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of protective effect of seminal exosomes on the quality of Frozen-Thawed Sperms in oligoasthenoteratozoospermia men

Public title
Effect of seminal exosome on the quality of frozen sperm
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Normozoospermia men Oligoasthenoteratozoospermia men age of 25-40 years
Exclusion criteria:
Smokers varicocele genital infections hydrocele endocrine diseases such as diabetes
Age
From **25 years** old to **40 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization by equal blocks method will be done by sealedenvelope.com. Four studied groups are placed in blocks of size 8 (including 2 participants from each group).
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be a double-blind trial. The participants and statistician were unaware of the sample allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Room 604, 6th floor, Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1416753955
Approval date
2023-01-07, 1401/10/17
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.650

Health conditions studied

1

Description of health condition studied
Oligoasthenoteratozoospermia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
sperm motility
Timepoint
after sperm thawing
Method of measurement
CASA software

2

Description
total anti-oxidant capacity
Timepoint
after thawing
Method of measurement
Elisa kit

3

Description
mitochondrial membrane potential
Timepoint
after thawing
Method of measurement
flow cytometry

4

Description
DNA breakage
Timepoint
after thawing
Method of measurement
flow cytometry

5

Description
apoptosis
Timepoint

after thawing
Method of measurement
flow cytometry

6

Description
sperm count
Timepoint
after thawing
Method of measurement
neubauer lam

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: sperm of normozoospermic men incubate with exosomes extracted from men with oligoasthenoteratozoospermia (OAT)
Category
Treatment - Other

2

Description
Intervention group 2: sperm of OAT men incubate with exosomes extracted from normozoospermic men
Category
Treatment - Other

3

Description
Intervention group 3: sperm of OAT men incubate with exosomes extracted from OAT men .
Category
Treatment - Other

4

Description
CONTROL GROUP: sperm of normozoospermic men incubate with exosomes extracted from normozoospermic men
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Royan Institue
Full name of responsible person
Mohammad Ali Sadighi Gilani
Street address
Royan Institute, Royan Alley, East Hafez St., Banihashem St., Shahid Soleimani HWY (Resalat)
City
Tehran
Province
Tehran
Postal code
1665659911
Phone
+98 21 2233 9905
Email
ipd@royaninstitute.org

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Vice-Chancellor for Research and Technology, Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3619
Email
tums_edu@tums.ac.ir
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
Fardin Amidi

Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
Street address
Faculty of Medical Sciences; Poursina Street; Qods street; Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 6405 3411
Email
amidifardin@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fardin Amidi
Position
PROFESSOR
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Biology
Street address
pour sina St, faculty of medical science
City
tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 6405 3411
Email
amidifardin@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Saeede Rezaei
Position
student
Latest degree
Master
Other areas of specialty/work
Reproductive Biology
Street address
Faculty of Medical Sciences; Poursina Street; Qods street; Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 6405 3404
Email
sr.13t66@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable