

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 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                                          |  | Tehran                                         |
| <b>Public title</b>                                                                                                                                                     |  | <b>Province</b>                                |
| Effect of seminal exosome on the quality of frozen sperm                                                                                                                |  | Tehran                                         |
| <b>Purpose</b>                                                                                                                                                          |  | <b>Postal code</b>                             |
| Treatment                                                                                                                                                               |  | 1416753955                                     |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                     |  | <b>Approval date</b>                           |
| <b>Inclusion criteria:</b>                                                                                                                                              |  | 2023-01-07, 1401/10/17                         |
| Normozoospermia men Oligoasthenoteratozoospermia men age of 25-40 years                                                                                                 |  | <b>Ethics committee reference number</b>       |
| <b>Exclusion criteria:</b>                                                                                                                                              |  | IR.TUMS.MEDICINE.REC.1401.650                  |
| Smokers varicocele genital infections hydrocele endocrine diseases such as diabetes                                                                                     |  | <b>Health conditions studied</b>               |
| <b>Age</b>                                                                                                                                                              |  | <u>1</u>                                       |
| From <b>25 years</b> old to <b>40 years</b> old                                                                                                                         |  | <b>Description of health condition studied</b> |
| <b>Gender</b>                                                                                                                                                           |  | Oligoasthenoteratozoospermia                   |
| Male                                                                                                                                                                    |  | <b>ICD-10 code</b>                             |
| <b>Phase</b>                                                                                                                                                            |  | <b>ICD-10 code description</b>                 |
| N/A                                                                                                                                                                     |  | <b>Primary outcomes</b>                        |
| <b>Groups that have been masked</b>                                                                                                                                     |  | <u>1</u>                                       |
| <ul style="list-style-type: none"> <li>Participant</li> <li>Data analyser</li> </ul>                                                                                    |  | <b>Description</b>                             |
| <b>Sample size</b>                                                                                                                                                      |  | sperm motility                                 |
| Target sample size: <b>100</b>                                                                                                                                          |  | <b>Timepoint</b>                               |
| <b>Randomization (investigator's opinion)</b>                                                                                                                           |  | after sperm thawing                            |
| Randomized                                                                                                                                                              |  | <b>Method of measurement</b>                   |
| <b>Randomization description</b>                                                                                                                                        |  | CASA software                                  |
| 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). |  | <u>2</u>                                       |
| <b>Blinding (investigator's opinion)</b>                                                                                                                                |  | <b>Description</b>                             |
| Double blinded                                                                                                                                                          |  | total anti-oxidant capacity                    |
| <b>Blinding description</b>                                                                                                                                             |  | <b>Timepoint</b>                               |
| This study will be a double-blind trial. The participants and statistician were unaware of the sample allocation.                                                       |  | after thawing                                  |
| <b>Placebo</b>                                                                                                                                                          |  | <b>Method of measurement</b>                   |
| Not used                                                                                                                                                                |  | Elisa kit                                      |
| <b>Assignment</b>                                                                                                                                                       |  | <u>3</u>                                       |
| Parallel                                                                                                                                                                |  | <b>Description</b>                             |
| <b>Other design features</b>                                                                                                                                            |  | mitochondrial membrane potential               |
| <b>Secondary Ids</b>                                                                                                                                                    |  | <b>Timepoint</b>                               |
| empty                                                                                                                                                                   |  | after thawing                                  |
| <b>Ethics committees</b>                                                                                                                                                |  | <b>Method of measurement</b>                   |
| <u>1</u>                                                                                                                                                                |  | flow cytometry                                 |
| <b>Ethics committee</b>                                                                                                                                                 |  | <u>4</u>                                       |
| <b>Name of ethics committee</b>                                                                                                                                         |  | <b>Description</b>                             |
| Ethics committee of Tehran University of Medical Sciences                                                                                                               |  | DNA breakage                                   |
| <b>Street address</b>                                                                                                                                                   |  | <b>Timepoint</b>                               |
| Room 604, 6th floor, Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.                                                               |  | after thawing                                  |
| <b>City</b>                                                                                                                                                             |  | <b>Method of measurement</b>                   |
|                                                                                                                                                                         |  | flow cytometry                                 |
|                                                                                                                                                                         |  | <u>5</u>                                       |
|                                                                                                                                                                         |  | <b>Description</b>                             |
|                                                                                                                                                                         |  | apoptosis                                      |
|                                                                                                                                                                         |  | <b>Timepoint</b>                               |

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