

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effect of GM-CSF cytokine on sperm parameters, PI3 kinase / AKT signaling pathway and glucose transporter in oligoasthenoteratospermia and azoospermia men

#### Protocol summary

##### Study aim

Evaluation of the effect of GM-CSF cytokine on sperm parameters, PI3 kinase / AKT signaling pathway and glucose transporter in oligoasthenoteratospermia and azoospermia men.

##### Design

Clinical trial with control group and parallel groups, and sample size of 40.

##### Settings and conduct

20 Obstructive azoospermia patients and 20 Oligoasthenoteratozoospermia patients who have male infertility factor, according to WHO criteria, are selected for sampling by referring to the Shahid Akbarabadi Hospital of Iran University of Medical Sciences. Each of the samples is divided into two groups; experiment, and control. In experimental group samples are incubated with 2 ng / ml GM-CSF for one hour, yet, in the control group, the sperms are incubated without GM-CSF for the same period of time. After oocyte collection, The eggs are divided into 2 groups. Half of the oocytes were inseminated with sperm that incubated with GM-CSF and remaining oocytes were inseminated with sperm from the control group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: infertile couples with male factor

Exclusion criteria: infertile couples with female factor

##### Intervention groups

Intervention group: Sperm incubation is performed in a medium containing GM-CSF for one hour. Control group: Sperm incubation is performed in a GM-CSF-free medium for one hour.

##### Main outcome variables

Sperm parameters, DNA fragmentation index, mitochondrial membrane potential, expression of PI3k, AKT and GLUT genes, expression of AKT and GLUT proteins, fertilization rate, embryo quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200519047508N1**

Registration date: **2020-05-30, 1399/03/10**

Registration timing: **prospective**

Last update: **2020-05-30, 1399/03/10**

Update count: **0**

##### Registration date

2020-05-30, 1399/03/10

##### Registrant information

##### Name

Fatemeh Tanhaye Kalate Sabz

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8670 2030

##### Email address

tanhaykalateh.f@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2021-01-17, 1399/10/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the effect of GM-CSF cytokine on sperm parameters, PI3 kinase / AKT signaling pathway and glucose transporter in oligoasthenoteratospermia and azoospermia men

## Public title

"The effect of GM-CSF cytokine on sperm"

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Men with semen parameters such as sperm count, motility and morphology, lower than WHO reference values Men with Obstructive Azoospermia

### Exclusion criteria:

Women over the age of 35, endometriosis, Polycystic ovary syndrome, Recurrent miscarriage

## Age

No age limit

## Gender

Male

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 40

## 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

Ethics committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2020-04-05, 1399/01/17

#### Ethics committee reference number

IR.IUMS.FMD.REC.1399.085

## Health conditions studied

### 1

#### Description of health condition studied

Male factor infertility, evaluation of the effect of GM-CSF

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Sperm motility

#### Timepoint

Assessments of sperm motility at the beginning of the study and after incubation in both intervention and control groups

#### Method of measurement

Optical microscope

### 2

#### Description

Mitochondrial membrane potential of sperm

#### Timepoint

Measurement of mitochondrial membrane potential after incubation in both intervention and control groups

#### Method of measurement

Jc- 1, Flow cytometry

### 3

#### Description

Sperm DNA fragmentation

#### Timepoint

Measurement of sperm DNA fragmentation after incubation in both intervention and control groups

#### Method of measurement

TUNEL method

### 4

#### Description

Fertilization Rate

#### Timepoint

24 hours after ICSI procedure

#### Method of measurement

View of 2 pronucleus with invert microscope

### 5

#### Description

Quality of embryo

#### Timepoint

Three days post-oocyte retrieval

#### Method of measurement

Using a three-point scoring system including fragmentation rate, number of blastomere, shape and size

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: After washing, the sperms are incubated with medium containing 2 ng / ml GM-CSF for one hour, then they used for ICSI

#### Category

Treatment - Other

### 2

#### Description

Control group: After washing, the sperms are incubated with an environment without GM-CSF for one hour. After that, they used for ICSI.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Akbarabadi hospital

##### Full name of responsible person

Fatemesadat Amjadi

##### Street address

Bagh Ferdos Station; before Mowlavi cross section road; Mowlavi Ave

##### City

Tehran

##### Province

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##### Postal code

1168743514

##### Phone

+98 21 5560 6034

##### Email

akbarabadihosp@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Seyed Abas Motevalian

##### Street address

Iran University of Medical Sciences; Next to Milad

Tower; Hemmat Highway

##### City

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##### Province

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1449614535

##### Phone

+98 21 86701

##### Email

PR@iums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Mahnaz Ashrafi

##### Position

Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Gynecology and Obstetrics

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Iran University of Medical Sciences; Next to Milad Tower; Hemmat Highway

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##### Province

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences  
**Full name of responsible person**  
Mahnaz Ashrafi  
**Position**  
Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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Fatemeh Tanhaye Kalate Sabz  
**Position**  
Ph.D student  
**Latest degree**  
Master

**Other areas of specialty/work**  
Reproductive Biology  
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fateme.1694@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

"There is no further information"

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

No - There is not a plan to make this available