

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

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Tehran

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1168743514

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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

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Iran University of Medical Sciences; Next to Milad

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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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Person responsible for updating data

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Latest degree
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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