

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Evaluation of the response to treatment with FSH in patients with oligoasthenospermia with different levels of DFI

#### Protocol summary

##### Study aim

Predictive evaluation of DFI in response rate to treatment with FSH

##### Design

clinical trial without control group with single groups and not blinded

##### Settings and conduct

This clinical study is conducted on infertile male patients referring to urology clinic of Imam Reza Hospital in Mashhad. All patients will take the test of sperm DNA fragmentation index and will then, based on the DNA damage, be divided into 3 groups: 1- Group with SDI of lower than 0.15 (excellent fertility) 2- Group with SDI of 0.15 to 0.3 (medium fertility) 3- Group with SDI of higher than 0.3 (poor fertility) All patients under study with Spermogram are required to take hormone tests which include measurement of FSH, LH, and testosterone levels in addition to DNA Fragmentation Index (DFI) test. All patients will also be clinically examined in order to be sure there is no structural problem

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient has an infertility problem, Patient is not under any other treatment or does not have any indication of surgery, oligoasthenospermia, Patient does not have any background anatomical problems in urogenital system, Patient's spouse is absolutely healthy in terms of fertility and has no problems Exclusion criteria: Creation of any anatomical disorder like Varicocele in urogenital system during the research, History of any previous medical intervention or previous surgery

##### Intervention groups

Use of subcutaneous FSH in treatment of idiopathic oligoasthenospermia every other day for 6 months with dosage of 150 mg and comparison of Spermogram factors, hormone profile and sperm DNA damage before and after treatment

##### Main outcome variables

Spermogram, DNA fragmentation index (DFI),

complications, hormone tests

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101130005280N28**

Registration date: **2019-07-14, 1398/04/23**

Registration timing: **prospective**

Last update: **2019-07-14, 1398/04/23**

Update count: **0**

##### Registration date

2019-07-14, 1398/04/23

##### Registrant information

##### Name

Raheleh Nejati

##### Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3711 2540

##### Email address

nejatir2@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-23, 1398/05/01

##### Expected recruitment end date

2021-01-20, 1399/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the response to treatment with FSH in patients with oligoasthenospermia with different levels of DFI

**Public title**  
Evaluation of the effect of FSH in treatment of oligoasthenospermia

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patient has an infertility problem Patient is not under any other treatment or does not have any indication of surgery oligoasthenospermia Patient does not have any background anatomical problems in urogenital system Patient's spouse is absolutely healthy in terms of fertility and has no problems  
**Exclusion criteria:**  
Creation of any anatomical disorder like Varicocele in urogenital system during the research History of any previous medical intervention or previous surgery

**Age**  
From **20 years** old to **45 years** old

**Gender**  
Male

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Central Building of Mashhad University of Medical

Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9138813944

#### Approval date

2019-04-16, 1398/01/27

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.175

## Health conditions studied

### 1

#### Description of health condition studied

Oligoasthenospermia

#### ICD-10 code

R86.9

#### ICD-10 code description

Unspecified abnormal finding in specimens from male genital organs

## Primary outcomes

### 1

#### Description

Spermogram

#### Timepoint

before and after treatment (6 months after medication use)

#### Method of measurement

Laboratory sampling

### 2

#### Description

Test of DNA damage in sperm (DNA fragmentation index)

#### Timepoint

before and after treatment (6 months after medication use)

#### Method of measurement

Laboratory sampling

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Use of subcutaneous FSH in treatment of idiopathic oligoasthenospermia every other day for 6 months with dosage of 150 mg and comparison of Spermogram factors, hormone profile and sperm DNA damage before and after treatment

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Mohsen Seyedi

**Street address**

Imam Reza Hospital, Imam Reza Square, Ebn\_e\_Sina Avenue

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3858 3885

**Email**

seyediVM911@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

**City**

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**Phone**

+98 51 3841 2081

**Email**

ramresearch@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Seyedi

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

**Street address**

Imam Reza Hospital, Imam Reza Square, Ebn\_e\_Sina Avenue

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**Province**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Salman Soltani

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Seyedi

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

**Street address**

Imam Reza hospital, Imam Reza Square, Ebn\_e\_Sina Avenue

**City**

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**Email**

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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**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data can be shared after patients are made unidentifiable.

**When the data will become available and for how long**

Data can be accessible 6 months after results are published.

**To whom data/document is available**

Data will be available for researchers in universities and other scientific institutes.

**Under which criteria data/document could be used**

Carrying out analysis on data is permitted.

**From where data/document is obtainable**

Data can be accessible through sending an email to the corresponding author.

**What processes are involved for a request to access data/document**

After sending a request email to the corresponding author, data will be sent in 1 month.

**Comments**