Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 with 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
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Raheleh Nejati
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Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital
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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

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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

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Sponsors / Funding sources

1

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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

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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