Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect rhFSH drug on sperm parameters,choromatin status and clinical outcomes of infertile men candidates for ICSI

Protocol summary

Study aim
The effect rhFSH drug on sperm parameters,choromatin status and clinical outcomes of infertile men candidates for ICSI

Design
A clinical trial with a control group with parallel, randomised groups

Settings and conduct
In the intervention group, patients with oligo-spermatozoa who received rhFSH at 75 IU for 2 or 3 months, serum samples and serum samples after taking the drug were taken into sterile containers for different tests (sperm analysis with WHO-2010 benchmark and DNA damage) and the place where the study was conducted is the specialized center for the treatment of infertility in the Qom Islamic Jihad.

Participants/Inclusion and exclusion criteria
Inclusion criteria: male infertile oligospermia ؛ Low levels of FSH in these individuals Exclusion criteria: Men have (varicocele ؛ history of varicoceles surgery ؛ systemic disease or taking medication for systemic disease ؛ history of chemotherapy or radiation therapy ؛ anatomical problems in the genitals ؛ including testicular atrophy ؛ treatment with antidepressants)

Intervention groups
1-Control group : In the control group, at least 25 patients with infertility, an ICSI candidate who was not treated with rhFSH, and a sperm analysis based on WHO-2010 WHO-2010 benchmark criteria and DNA damage, and blood serum samples were taken to measure hormones (T, LH, FSH). 2- Intervention group : At least 25 ICSI patients who had been treated with rhFSH for 2 or 3 months, and serum samples were taken for hormonal measurements (T, LH, FSH) and semen samples collected after drug administration for different tests (sperm analysis The WHO-2010 benchmark criteria and DNA damage).

Main outcome variables
Sperm parameters; DNA damage; examination of fertilization status; embryo quality; pregnancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170923036334N2**
Registration date: **2018-09-02, 1397/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-02, 1397/06/11**
Update count: **0**

Registration date
2018-09-02, 1397/06/11

Registrant information

Name
Atefeh Verdi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 25 3291 7757

Email address
verdi@acecr.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-16, 1396/11/27

Expected recruitment end date
2018-09-18, 1397/06/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect rhFSH drug on sperm parameters,choromatin status and clinical outcomes of infertile men candidates for ICSI

Public title
The effect rhFSH drug in infertile men

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Oligozospermia infertile men

Exclusion criteria:
Men with varicocele, history of varicoceles surgery, systemic disease or taking medication for systemic disease, chemotherapy or radiotherapy history, anatomical problems in the genitals, including testicular atrophy, treatment with antidepressants, are excluded.

Age
From **25 years** old to **45 years** old

Gender
Male

Phase
1-2

Groups that have been masked

- Participant

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, simple individual randomization by use of randlist software is applied.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, participants were not aware of the drug dose and efficacy in knowing the use of the drug, which is why they are blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Islamic Azad University Medical Sciences

Street address
5 unit., Hafez Bilding., khalili Ave., Salarieh street

City
Qom

Province
Ghoum

Postal code
3716963895

Approval date
2018-02-13, 1396/11/24

Ethics committee reference number
IR.IAU.Qom.REC.1396.56

Health conditions studied

1

Description of health condition studied
oligospermia

ICD-10 code
n00-n99

ICD-10 code description
XIV بیماریهای سیستم تناسلی

Primary outcomes

1

Description
Sperm parameters

Timepoint
In this study, the evaluation of sperm parameters before and after rhFSH is evaluated and the rate of use of rhFSH is three months.

Method of measurement
Clinical analysis of semen standard for sperm parameters with the usual laboratory method and optical microscope according to WHO-2010 WHO criteria.

2

Description
DNA Damage

Timepoint
In this study, the evaluation of DNA damage before and after taking rhFSH is measured and the rate of use of rhFSH is three months.

Method of measurement
DNA damage is done using the SDF laboratory kit and optical microscope.

3

Description
The amount of hormone FSH

Timepoint
In this study, the amount of FSH is measured before and after the administration of the drug, and the rate of use of rhFSH is three months.

Method of measurement
Measurement of FSH levels is done by ELIZA commercial kits.

Secondary outcomes

1

Description
Check fertilization rates
Timepoint
One day after sperm injection into the oocyte cytoplasme .
Method of measurement
Fertilization can be seen with an inverted microscope.

2

Description
Quality of the embryo
Timepoint
Three days after sperm injection into oocyte cytoplasm
Method of measurement
Evaluating the quality of the embryo is based on the number of cells and the number of blastomers and the fragmentation of the blastomers and is observed with the Invert microscope.

3

Description
Pregnancy
Timepoint
14 days after the transfer of the embryo into the uterus
Method of measurement
Pregnancy testing is done by giving beta-HCG.

Intervention groups

1

Description
1-Control group:In the control group, at least 25 ICSI patients were not treated with rhFSH and sperm analysis was performed based on WHO-2010 criteria and DNA damage and blood serum was taken to measure hormones (T, LH, FSH)) be done.
Category
Treatment - Other

2

Description
2-Intervention group: At least 25 patients with oligo-spermatozoa who were treated with rhFSH (gel) for a period of 2 or 3 months (twice a week for subcutaneous injection), and serum samples were taken to measure hormones (T, LH, FSH). And the semen is prepared after taking the medication (between 48 and 72 hours from the closest approach) into sterile containers for various tests (sperm analysis, based on WHO-2010 benchmark criteria and DNA damage).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Treatment Highly Specialized Center of ACECR Qom
Full name of responsible person
Atefeh Verdi
Street address
5 unit., Hafez Bilding., khalili Ave., Salarieh street
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Atefeh.Verdi@Yahoo.Com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Mohammad Mahdi Jabbari
Street address
Km 5 Sadra City, Islamic Azad University of Shiraz
City
shiraz
Province
Fars
Postal code
7473171987
Phone
+98 71 3641 0041
Fax
+98 71 3641 0059
Email
jabbari@fsriau.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
Islamic Azad University

Full name of responsible person
Atefeh Verdi

Position
Ph.D. student

Latest degree
Master

Other areas of specialty/work
Others

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Position
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Person responsible for updating data

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Atefeh verdi

Position
Ph.D. student

Latest degree
Master

Other areas of specialty/work
Others

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

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

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

Title and more details about the data/document
Other than personal data, the rest of the consequences and variables can be shared

When the data will become available and for how long
6 months after printing results

To whom data/document is available
Employed researchers in Academic and academic institutions

Under which criteria data/document could be used
Provide accurate information to the urologist to treat infertility and patients' well-being

From where data/document is obtainable
Atefe Verdi (09128528559) atefeh.verdi@yahoo.com

What processes are involved for a request to access

data/document	Access the data by reading the article
Comments	