

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

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

Protocol summary

Study aim

The effect rhFSH drug on sperm parameters, chromatin 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 sperm 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

Ghous

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 cytoplasm

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) to 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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Fax

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Email

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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Atefeh Verdi

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Atefeh verdi

Position

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Latest degree

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Other areas of specialty/work

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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

Atefeh 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