

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

A randomized clinical trial comparing the effect of intraovarian and subcutaneous injection of corifollitropin alfa in the Duostim protocol in infertile women with premature ovarian failure and poor responders candidates for IVF

Protocol summary

Study aim

Fertility in women with poor ovarian response is one of the challenges ahead. In this study, the Dostim protocol is performed using rFSH as a single intraovarian injection on the day of egg retrieval, and then the Dostim cycle continues. We have decided to perform the Dostim protocol in the form of intraovarian injection, but with CORIFOLLITROPIN ALFA (elonva) instead of rFSH and compare it with the subcutaneous injection of the same drug with the same protocol. Corifollitropin alfa (Elonova).

Design

CLINICAL TRIAL with a control group without blinding was randomized on 3-people (15 people in each group)
randomization method: two-allele random blocks - size 4

Settings and conduct

The study is conducted in the infertility clinic of Imam Khomeini Hospital in Tehran. Comparison of Dostim diet by intraovarian and subcutaneous injection

Participants/Inclusion and exclusion criteria

Inclusion criteria 1- Age 32 to 42 years 2-BMI ≤ 30 3- Poor responder cases with abnormal biomarkers 4- History of non-response in previous cycles (less than 3 oocytes) or first IVF experience 5-Sperm analysis is normal or has the minimum necessary criteria for ICSI exit criteria History of autoimmune diseases - coagulation disorders - uterine anomalies - chromosomal and genetic disorders - chronic renal and metabolic diseases - hypo and hyperthyroidism - history of malignancy - endometriosis - history of repeated miscarriage and RIF

Intervention groups

Performing the Dostim protocol as an intraovarian injection, but with CORIFOLLITROPIN ALFA (elonva) instead of rFSH and comparing it with the subcutaneous injection of the same drug with the same protocol

Main outcome variables

Primary outcome: the number and quality of oocytes obtained
Secondary outcomes: number and quality of embryos obtained - biochemical pregnancy - total dose of gonadotropins consumed - and the final cost of treatment in each group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180409039247N6**

Registration date: **2023-05-30, 1402/03/09**

Registration timing: **prospective**

Last update: **2023-05-30, 1402/03/09**

Update count: **0**

Registration date

2023-05-30, 1402/03/09

Registrant information

Name

Marjan Ghaemibidgoli

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8800 4858

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial comparing the effect of intraovarian and subcutaneous injection of corifollitropin alfa in the Duostim protocol in infertile women with premature ovarian failure and poor responders candidates for IVF

Public title

A randomized clinical trial comparing the effect of intraovarian and subcutaneous injection of corifollitropin alfa in the Duostim protocol in infertile women with premature ovarian failure and poor responders candidates for IVF

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

BMI ≤ 30. Poor responder cases with abnormal biomarkers AFC : $\Delta \leq 5$, AMH < 0.5-1.1. History of non-response in previous cycles (less than 3 oocytes) or first ivf experience Sperm analysis is normal or has the minimum necessary criteria for ICSI

Exclusion criteria:

History of autoimmune diseases - coagulation disorders - uterine anomalies - chromosomal and genetic disorders - chronic renal and metabolic diseases - hypo and hyperthyroidism - history of malignancy - endometriosis - history of repeated miscarriage and RIF

AgeFrom **32 years** old to **42 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

One list of computerized randomization is created by an analyst who is blind to the trial. All participants are blind either. randomization is by blocking by WWW.Sealedenvelop.com by the epidemiologist. The blocks are size 6. : AAAABBBB-AAABBBBA-AAABBBAB-AAABBAABB-AABBBBAA-AABBAABB-AABBBBAAB intervention group: intraovarian injection and control group: routine treatment (subcutaneous injection)

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 in the research of Imam Khomeini hospital complex

Street address

Imam complex, East Bagherkhan street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2023-03-15, 1401/12/24

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.015

Health conditions studied**1****Description of health condition studied**

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

The number and quality of oocytes obtained

Timepoint

On the day of puncture

Method of measurement

The number of eggs obtained on the day of puncture with OPU catheter

2**Description**

Number and quality of obtained embryos

Timepoint

The day after the puncture in the embryology laboratory

Method of measurement

Under the microscope in the embryology laboratory by the embryologist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dostim protocol is performed as an intraovarian injection but with CORIFOLLITROPIN ALFA (elonva) instead of rFSH on the day of egg retrieval in the operating room, and then the routine cycle of Dostim continues.

Category

Treatment - Drugs

2

Description

Control group: Dustim protocol is administered as a subcutaneous injection but with CORIFOLLITROPIN ALFA (elonva) instead of rFSH on the day of egg retrieval in the operating room, and then the Dostim routine cycle continues.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Complex

Full name of responsible person

Firoozeh Rakhshani

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East Bagherkhan street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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Quds St. intersection with Keshavarz Blvd

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Firoozeh Rakhshani

Position

fellowship infertility

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Position
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Latest degree
Specialist
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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available