

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between administration of FSH plus HCG versus HCG alone for triggering ,in the results of ICSI

Protocol summary

Study aim

comparision between administration of FSH plus HCG versus HCG alone for triggering, in the results of ICSI

Design

Clinical trials with community based and pragmatic control group, with parallel groups,one blind, randomized.

Settings and conduct

This study was conducted as a randomized one blind clinical trial. Normoresponder women who are referred to the avicenna Infertility Center, are randomly divided into two groups of 40, between the end of 1997 and the beginning of 1998 who are candidates for ICSI cycles. . Starting ultrasound in the case of a thin endometrium and lack of vision of the ovarian follicle larger than 10 millimeters of the antagonist cycle begins. The initial dose of gonadotrophin is based on age, weight, ovarian reserve and previous response to COH, and ultrasound and the visit are performed 5 days later, and then every 3-2 days. Dosage adjustment is based on follicular growth. The drugs used to stimulate the gonadotropin releasing hormone (GnRH) agonist and the gonadotropin releasing hormone (GnRH) antagonist ovaries.

Participants/Inclusion and exclusion criteria

Inclusion Criteria : Candidate entering the ICSI cycle, ages 19 to 41 years, BMI between 18 and 30 AFC greater than or equal to 5 on the third day of the cycle, FSH on the third day of the cycle is less than 12. exclusion criteria: Endometriosis Grade 3 and 4, Ovulation induction contraindications, Severe male factor infertility diagnosis, history of 2 or more previous IVF or ICSI cycles.

Intervention groups

Infertile normoresponder Women Candidate ICSI Cycle,randomly divide in two 40 members groups.First group receive FSH with HCG at triggering time,second group receive only HCG.

Main outcome variables

From the degree of chemical pregnancy (β HCG positive), the rate of implantation (seeing a pregnancy sack in

sonography) and the clinical pregnancy rate (seeing fetal heart rate in ultrasound) are examined.

General information

Reason for update

Acronym

FSH for triggering

IRCT registration information

IRCT registration number: **IRCT20190108042285N1**

Registration date: **2019-01-19, 1397/10/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-19, 1397/10/29**

Update count: **0**

Registration date

2019-01-19, 1397/10/29

Registrant information

Name

Nayereh Tamizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 23519

Email address

n.tamizi@ari.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-19, 1397/10/29

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparison between administration of FSH plus HCG versus HCG alone for triggering ,in the results of ICSI

Public title
FSH for triggering in ICSI

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for the ICSI Cycle FSH of the third day of the cycle less than 12 AFC more or equal 5 BMI between 18 and 30

Exclusion criteria:
Infertility with severe male factor A history of twice as many ICSI or IVF Previous cycles Endometriosis Grade 3 and 4 contraIndications for ovulation induction

Age
From **19 years** old to **41 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into two equal groups (A and B) based on a randomized design with six blocks that are designed using random allocation software.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study population, taking into account that in the general process of treatment of ICSI, multiple injections of injections (at least 6 days) and only the last injection in the study group receive an additional injection every day (from the same type of ampoule that was received daily from day before Have blinded themselves to what group, study or control are. Data analysis with group A and group B data analysis, so that information on intervention on the user group is not known.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Avicenna Research Institute for Biotechnology, Jihad University

Street address

Shariati St. Tehran, Tehran province, Iran

City

Tehran

Province

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Postal code

1941913114

Approval date

2018-12-31, 1397/10/10

Ethics committee reference number

IR.ACECR.AVICENNA.REC.1397.016

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

The amount and quality of the oocyte is obtained

Timepoint

time of ovary puncture

Method of measurement

embriologist assey

2

Description

chemical pregnancy care

Timepoint

16 days later receive HCG

Method of measurement

beta HCG

Secondary outcomes

1

Description

clinical pregnancy rate

Timepoint

7 weeks of pregnancy

Method of measurement

sonography

2

Description

implantation rate

Timepoint

5 weeks of pregnancy

Method of measurement

sonography

Intervention groups

1

Description

Intervention group: Normally, the women are candidates for the ICSI cycle, and the first group consists of 40 people. In this group, in addition to receiving 10,000 units of HCG, 450 gonadotropin-releasing hormone (GnRH) is administered to the Trigger Rur.

Category

Treatment - Drugs

2

Description

Control group: The group, which includes 40 sexually transmitted ICSI candidates, receives 10,000 units of HCG during the trigger.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Avecinna Infertility Treatment Center

Full name of responsible person

Dr Soheila Ansari-pour

Street address

SHARIATI

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Soh.ansari-pour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and

research

Full name of responsible person

Mohammad Reza Sadeghi

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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

Iranian academic center for education culture and research

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

Iranian academic center for education culture and research

Full name of responsible person

Dr. Tamizi Nayereh

Position

infertility flowship assistant

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Dr. Ansaripour Soheila

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Dr.Tamizi.Nayereh

Position

Gynecologist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

non ethical

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