Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparision 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 verusus 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 gonal F and menopause 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 (βHCG 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

Comparision 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, Jahad University

Street address

Shariati St. Tehran, Tehran province, Iran

City

Tehran

Province

Tehran

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 pergnancy
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 gonal F (FSH) 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 Ansaripour
Street address
SHARIATI
City
TEHRAN
Province
Tehran
Postal code
1941913114
Phone
+98 21 2264 4710
Email
Soh.ansaripour@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
Street address
shariati St.
City
Tehran
Province
Tehran
Postal code
1941913114
Phone
+98 21 2243 2020
Email
Soh.ansaripour@gmail.com
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
infertillity fllowship assistant
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Shariati St.
City
Tehran
Province
Tehran
Postal code
1941913114
Phone
+98 21 2264 4710
Email
dr.nayereh.tamizi@gmail.com

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

Street address
shariati St.

City
Tehran

Province
Tehran

Postal code
1941913114

Phone
+98 21 2264 4710

Email
Soh.ansaripour@gmail.com

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

Street address
shariati St.

City
Tehran

Province
Tehran

Postal code
1941913114

Phone
+98 21 2264 4710

Email
dr.nayereh.tamizi@gmail.com

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