Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison between FSH administration with HCG and HCG alone at the time of trigger in IVF cycles outcomes

Protocol summary

Study aim

The aim of this randomized clinical trial is comparison of the effect of FSH (follice - stimulating hormone) administration plus HCG(human chorionic gonadotropin) at the time of oocyte trigger and HCG alone on IVF cycles outcomes as well as ovarian hyperstimulatiopn syndrom.

Design

A total of 109 women who met inclusion criteria, who were convinced about the research design and signed a written consent form were divided into two groups during a not-blinded, phase 2, parallel groups, without control group randomized clinical trial.

Settings and conduct

Regarding the importance of oocyte triggering in IVF cycles, 109 women at Yazd Research and Clinical Center who were candidate for IVF, were randomly divided into two groups for oocyte triggering (one group using FSH plus hCG or hCG alone in another group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women undergoing IVF and GnRH antagonist protocol. Non inclusion criteria: severe male factor infertility, cycle cancellation due to changing to intrauterine insemination and freeze-all policy, a cycle containing preimplantation genetic diagnosis (PGD) and estradiol level of more than 2500 pg/mL, donor or surrogate cycle.

Intervention groups

Intervention group 1: Oocyte triggering using FSH plus hCG; Intervention group 2: Oocyte triggering using hCG alone

Main outcome variables

Clinical pregnancy; oocyte recovery rate; oocyte maturity rate; fertilization proportion rate; fertilization rate; implantation rate; chemical pregnancy

General information

Reason for update

Updating the clinical trial according to the last changes in case number and results

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082724512N5**
Registration date: **2017-09-22, 1396/06/31**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-23, 1400/01/03**
Update count: **2**

Registration date

2017-09-22, 1396/06/31

Registrant information

Name

Abbas Aflatoonian

Name of organization / entity

Yazd research and clinical center for infertility

Country

Iran (Islamic Republic of)

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+98 358247085

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Recruitment status

Recruitment complete

Funding source

Yazd Reproductive Sciences Institute ,Shahid Sadoughi University of Medical Sciences.

Expected recruitment start date

2017-08-01, 1396/05/10

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

2017-08-01, 1396/05/10

Actual recruitment end date

2017-10-07, 1396/07/15

Trial completion date

2017-11-30, 1396/09/09

Scientific title
Comparison between FSH administration with HCG and HCG alone at the time of trigger in IVF cycles outcomes

Public title
The effect of FSH administration with HCG at the time of trigger on IVF cycles outcomes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women who candidate for IVF cycles underwent GnRH antagonist protocol Fresh embryo transfer cycles
Exclusion criteria:
Women with history of endocrine disorders serum estradiol>2500pg/ml in day of trigger Intrauterine abnormality (uterine polyp; uterine myoma) Severe male factor Cycle cancellation or changing to intrauterine insemination A cycle containing preimplantation genetic diagnosis (PGD) Women who did not undergo embryo transfer due to the freeze-all policy Donor or surrogate cycle
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **152**
Actual sample size reached: **109**
Randomization (investigator's opinion)
Randomized
Randomization description
A number of 109 women who met inclusion criteria were explained about the procedure and after signing the written consent form, divided randomly into two groups using random numbers table.
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 of Yazd Reproductive Sciences Institute Shahid Sadoughi University
Street address
yazd Reproductive Sciences Institute,Bouali Ave.,Safaeyeh,Yazd,Iran.
City
Yazd
Province
Yazd
Postal code
8916877391
Approval date
2017-05-21, 1396/02/31
Ethics committee reference number
IR.SSU.RSI.REC.1396.7

Health conditions studied

1

Description of health condition studied
Female infertility
ICD-10 code
N97.9
ICD-10 code description
Female infertility,unspecified

Primary outcomes

1

Description
chemical pregnancy
Timepoint
14 days after transfer
Method of measurement
BHCG test

2

Description
clinical pregnancy
Timepoint
2 weeks after positive BHCG
Method of measurement
Transvaginal sonography

Secondary outcomes

1

Description
Fertilization proportion
Timepoint
Post oocyte retrival
Method of measurement
The number of fertilized oocytes divided by the total number of oocytes

2

Description
oocyte recovery rate
Timepoint
After oocyte retrieval

Method of measurement
The number of retrieved oocytes divided by the number of follicles >10 mm in size counted on the day of trigger

3

Description
oocyte maturity rate
Timepoint
After oocyte retrieval
Method of measurement
the number of metaphase II (MII) oocytes divided by the number of oocytes retrieved

4

Description
Fertilization rate
Timepoint
After formation of 2PNs
Method of measurement
the number of 2PNs divided by the total number of MII oocytes

5

Description
Implantation rate
Timepoint
After detection of gestational sac in ultrasonography
Method of measurement
the number of intrauterine gestational sacs observed by transvaginal ultrasonography divided by the total number of transferred embryos

Intervention groups

1

Description
Patients in the first intervention group received injection of 450 IU FSH with 5000 IU hCG once on the day of oocyte triggering.
Category
Treatment - Drugs

2

Description
Patients in the second intervention group received injection of 5000 IU hCG once on the day of oocyte triggering.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Reproductive Sciences Institute
Full name of responsible person
Dr. Abbas Aflatoonian,Professor of Shahid Sadoughi University of Medical Sciences
Street address
Yazd Reproductive Sciences Institute,Bouali Ave. Safaeiyeh,Yazd
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+98 35 3824 7087
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abbas-aflatoonian@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology, Shahid Sadoughi University
Full name of responsible person
Masoud Mirzaei
Street address
Bahonar square
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Postal code
8916978477
Phone
+98 35 3146 2136
Email
dvc.research@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research and Technology, Shahid Sadoughi University
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
Yazd Reproductive Sciences Institute
Full name of responsible person
Pro. Abbas Aflatoonian
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Yazd Reproductive Sciences Institute
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Dr.Saeideh Dashti
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Latest degree
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saeideh_dashti@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All participant data can be shared after making people unidentifiable
When the data will become available and for how long
Once data publication
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
Journal who publishes the results
From where data/document is obtainable
Yazd Reproductive Sciences Institute, Bouali Ave, Yazd, Iran. +98353 8247085 Dr. Saeedeh Dashti
What processes are involved for a request to access data/document
Two months after the submission of application
Comments