Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The effect of androgen administration on IVF outcome in poor responders undergoing ovarian stimulation with microdose protocol

Protocol summary

Study aim
Study the effect of androgen administration on IVF outcome in poor responders undergoing ovarian stimulation with microdose protocol
Design
Two arm parallel grou randomised trial
Settings and conduct
Infertile woman refer to reproductive sciences institute
Participants/Inclusion and exclusion criteria
Poor responders Sever endometriosis, Sever male factor, Uncontrol endocrine disease
Intervention groups
Study the effect of adding androgen to ovarian stimulation with microdose protocol in study group and comparison with only microdose protocol in control group on IVF outcome in poor responders
Main outcome variables
Clinical pregnancy, Chemical pregnancy, Fetus number,Oocyte number, Dominant follicle

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180818040828N1**
Registration date: **2018-10-18, 1397/07/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-20, 1400/01/31**
Update count: **1**
Registration date
2018-10-18, 1397/07/26

Registrant information
Name
Lida Saeed
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 34 3132 8000
Email address
lsaeid@kmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-09-23, 1397/07/01
Expected recruitment end date
2018-11-22, 1397/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of androgen administration on IVF outcome in poor responders undergoing ovarian stimulation with microdose protocol

Public title
The effect of androgen administration on IVF outcome in poor responders
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient with poor responder ovaries Age <45 years Age >18 years
Exclusion criteria:
Sever Endomtriosis Sever Male Factor Uncontrol Endocrine Disease
Age
From **18 years** old to **45 years** old
Gender

Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
At first the 60 qualified patients select and in order to refer from number 1 to 60 consider for them.Then with Random Allocation Software and random codes divide in two groups with 30 patients.
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 reproducive sciences institute-Yazd Shahid Sadoughi University of Medical Scien
Street address
Bouali Ave, Safaeih
City
Yazd
Province
Yazd
Postal code
8916877391
Approval date
2018-05-20, 1397/02/30
Ethics committee reference number
IR.SSU.RSI.REC.1397.001

Health conditions studied

1

Description of health condition studied
Patient with poor responder ovareis
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Clinical pregnancy
Timepoint
5 Week after embryo transfer
Method of measurement
Vaginal Sonography to see fetus in gestational sac

Secondary outcomes

1

Description
Chemical pregnancy
Timepoint
2 weeks after embryo transfer
Method of measurement
Check BHCG

2

Description
Fetus number
Timepoint
2-3 day after follicle aspiration
Method of measurement
Fetus in labratory

3

Description
Oocyte number
Timepoint
In follicular aspiration day
Method of measurement
To see oocytes in labratory

4

Description
The number of dominant follicle
Timepoint
In ovulation stimulation cycle
Method of measurement
Vaginal sonography

5

Description
Estradiol level in blood
Timepoint
To see 2-3number of >=17 mm follicle
Method of measurement
Check in labratoty

6

Description
Gonadotropin dosage
Timepoint

At the end of ovarian stimulation

Method of measurement

International Units

Intervention groups

1

Description

Intervention group: Since the 3rd day of menses will begin GnRH agonist buserelin acetate (Cinafact,cinagen,Iran) at a dose of 50 µg subcutaneously twice daily and menotropin(BSV,Germany) 325 IU daily intramuscular.Follicular size with sonography and serum FSH, LH, P, and E2 level will be measured on cyle day 7 and then every 2-3 days one time. When serum FSH levels exceeded 20 IU/L on cycle day 7 or any time thereafter and follicular growth will considered to be slow or asynchronous (when one or two leading follicles were ≥4 mm larger than the rest of the cohort), gonadotropins will discontinue for 2-5 days. 40.5 mg of daily transdermal testosterone (Androgel 1.62% , Abbvie) will begin from the day gonadotropin injections will interrupt until the day of the ovulation trigger. When at least two dominant follicles will reach to size of ≥17 mm, 10,000 IU hCG (Pregnyl, Netherlands) was administered subcutaneously for ovulation trigger. Thirty-six hours later, the oocytes were retrieved by means of ultrasound-guided transvaginal needle aspiration. Following egg retrieval, intracytoplasmic sperm injection/IVF will be done. The embryos will transferre at the cleavage stage 2-3 days later.

Category

Treatment - Drugs

2

Description

Control group:Since the 2d day of menses GnRH agonist buserelin acetate (Cinafact,cinagen,Iran) at a dose of 50 µg subcutaneously twice daily and since the 4th day menotropin(BSV,Germany) 325 IU daily intramuscular will begin.Follicular size with sonography will be measured on cyle day 9 and then every 2-3 days one time. In this group gonadotropin will not interrupt and will continue until trigger day. When at least two dominant follicles will reach to size of ≥17 mm,serum FSH,LH,P and E2 levels will be measured and10,000 IU hCG (Pregnyl, Netherlands) will administere subcutaneously for ovulation trigger. Thirty-six hours later, the oocytes were retrieved by means of ultrasound-guided transvaginal needle aspiration. Following egg retrieval, intracytoplasmic sperm injection/IVF will be done. The embryos will transferre at the cleavage stage 2-3 days later.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd reproductive sciences institute

Full name of responsible person

Dr.Abbas aflatoonian

Street address

Bouali Ave, Safaeih

City

Yazd

Province

Yazd

Postal code

8916877391

Phone

+98 35 3824 7085

Fax

+98 35 3824 7087

Email

abbas_aflatoonian@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr.Masoud Mirzaei

Street address

Bahonar Square, Yazd University of Medical Sceincese

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3724 0171

Fax

Email

Masoudmirzaei@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Dr.Lida Saeed
Position
Assistant professor, Infertility fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Bouali Ave, safaeih
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Fax
+98 35 3824 7087
Email
lsaeed6@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr.Abbas Aflatoonian
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Reproductive Science Institute, Boouali Ave,Safaeih
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Fax
+98 35 3824 7087
Email
abbas_aflatoonian@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr.Lida Saeed
Position
Assistant Professor, Infertility Fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
RReproductive Science Institute, Boouali Ave,Safaeih
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Fax
+98 35 3824 7087
Email
lsaeid@kmu.ac.ir

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
Due to the privacy of patients
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
Study protocol,statistical analysis map,clinical study report after article edition will be available
When the data will become available and for how long
After article edition
To whom data/document is available
Researchers that work in university
Under which criteria data/document could be used
In retrospective studies
From where data/document is obtainable
Yazd reproductive sciences institute
What processes are involved for a request to access data/document
Demand from Vice president of research,propound in Research council of infertility center and after acception refer to research expert and receive the data
Comments