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 group 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

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 reproductive 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 ovaries
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 laboratory

3
Description
Oocyte number
Timepoint
In follicular aspiration day
Method of measurement
To see oocytes in laboratory

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 2-3 number of >=17 mm follicle
Method of measurement
Check in laboratoty

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 cycle 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 cycle 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 and 10,000 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

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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 Science

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8915173160

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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
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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
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Yazd
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8916877391
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lsaeed@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, propose in Research council of infertility center and after acceptance refer to research expert and receive the data
Comments