Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing double dose and tirple dose of GNRH agonists in Endometriosis triggering undergoing ART cycle

Protocol summary

Study aim

comparing double dose and triple dose of GNRH agonists in Endometriosis triggering undergoing ART cycle.

Design

80 patients with definite diagnosis of endometriosis after selection based on inclusion and exclusion criteria and recording the initial data will be randomly divided into two groups of D who receive double dose and group T who receive triple dose.

Settings and conduct

All procedures are performed by a surgeon in a private referral endometriosis hospital (Dena Hospital - Shiraz - Iran).In all patients before oocyte stimulation, the required hormones level will be measured. primary vaginal ultrasound will be performed. controlled ovarian stimulation will be performed by recombinant FSH and GNRH antagonist. evaluation of follicles will be monitored by vaginal ultrasound. once the follicles have reached the required size, the final stimulation of the follicles will be performed with GNRH agonist drugs Without informing patients. the patients will be randomly divided into two groups. (single blind) one of them will recieve double dose and the other one will recieve triple dose of GNRH agonists.

Participants/Inclusion and exclusion criteria

Women with a definite diagnosis of endometriosis ,21-35 years

Intervention groups

80 patients with endometriosis under assisted reproductive therapy, after performing the necessary tests and diagnostic ultrasound that meet the inclusion criteria will be randomly divided into two groups of D and T. after stimulating the follicles, we will trigger the group D with double dose and group T with triple dose of GNRH agonists.

Main outcome variables

At the end of the study, maturation and function of ovums; fertilization and blastocyst conversion; ovarian hyperstimulation syndrome; implantation rate and clinical pregnancy will be determined and compared between the two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200925048836N2**
Registration date: **2022-01-21, 1400/11/01**
Registration timing: **prospective**

Last update: **2022-01-21, 1400/11/01**
Update count: **0**

Registration date

2022-01-21, 1400/11/01

Registrant information

Name

Elham Askary

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3233 2365

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-18, 1400/11/29

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing double dose and tirple dose of GNRH agonists in Endometriosis triggering undergoing ART cycle

Public title
The effect of different amounts of assisted reproductive drugs in endometriosis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with a definite diagnosis of endometriosis based on pathology report aged between 21 and 35 years, the first period of using ART method, normal serum FSH concentration in primary follicular phase , AMH>0.5, presence of both ovary , having the ART use indication that they are willing to participate in the study.
Exclusion criteria:
history of uterine and ovary surgery poly cystic ovarian syndrome triggering with HCG severe fertilizing disorder in spouse patient with hypo gonadotrpic hypogonadism and uterine abnormality

Age
From **21 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The treatment allocation list is already designed on Block Balanced Randomization Method by software (https://mahmoodsaghaei.tripod.com/Softwares/randalloc.html) (D), 2 (D), 3 (D), 4 (T), 5 (T),..... Any eligible patient will be given a 1 to 80 code after obtaining informed consent in order to visit the clinic and based on above block, they receive T or Ddrug. Patients information will be collected through an interview with the patients. Randomization will be performed by an experienced nurse using a random number table. The patient, embryologist, gynecologist and statistician will be unaware of the groupings.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients will receive T or D medication based on randomized block in double blind method and a code will be allocated to each patient (1 to 80) that will be encoded at the end of the study. The patients and the designer and drug distributer are not aware of the drug pack. This study is the second phase of trial .

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Headquarters Of Shiraz University of Medical Sciences - Zand St

City
Shiraz

Province
Fars

Postal code
34786-71946

Approval date
2021-06-12, 1400/03/22

Ethics committee reference number
IR.SUMS.MED.REC.1400.160

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Oocyte maturation

Timepoint
Before and after treatment

Method of measurement
Transvaginal sonography

Secondary outcomes

1

Description
Oocyte yield

Timepoint
Before and after treatment

Method of measurement
Transvaginal sonography and hormonal assay

Intervention groups

1

Description

In intervention group 1, on day 2 or 3 of the menstrual cycle, controlled ovarian stimulation with recombinant FSH (Gonal-f, merck senoro) at a dose of 175-112.5 IU / DAY will be performed for 4 days. FSH dose based on ovarian response and serum estradiol level It will be adjusted when the target follicle is more than 14 mm and the serum concentration of estradiol is more than 300 pg / ml. The antagonist-Ganirelix drug (Orgalutran, Organon) will be used at a subcutaneous dose of 0.25 mg / day. Follicle development will be monitored by transvaginal ultrasound with a 4-8 MHz vaginal probe. When the three follicles reach a diameter greater than 17 mm, the final maturation of the ovum will be performed with a single subcutaneous dose of 0.2 mg triptorelin (GNRH agonist). After 12 hours The same drug will be repeated at a dose of 0.1 mg. ovum pick up under vaginal ultrasound guidance will be performed 35 hours after the first dose under general anesthesia with a single lumen needle (Swemed, Vitrolife).

Category

Treatment - Drugs

2

Description

In intervention group 2, on day 2 or 3 of the menstrual cycle, controlled ovarian stimulation with recombinant FSH (Gonal-f, merck senoro) at a dose of 175-112.5 IU / DAY will be performed for 4 days. FSH dose based on ovarian response and serum estradiol level It will be adjusted when the target follicle is more than 14 mm and the serum concentration of estradiol is more than 300 pg / ml. The antagonist-Ganirelix drug (Orgalutran, Organon) will be used at a subcutaneous dose of 0.25 mg / day. Follicle development will be monitored by transvaginal ultrasound with a 4-8 MHz vaginal probe. When the three follicles reach a diameter greater than 17 mm, the final maturation of the ovum will be performed with a single subcutaneous dose of 0.2 mg triptorelin (GNRH agonist). After 12 hours The same drug will be repeated at a dose of 0.1 mg.12 hours later, triptorelin will be repeated at a dose of 0.1 mg. ovum pick up under vaginal ultrasound guidance will be performed 35 hours after the first dose under general anesthesia with a single lumen needle (Swemed, Vitrolife).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dena hospital fertility clinic

Full name of responsible person

Goudarzi Zahra

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Dena hospital, Zargari blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Askari Elham

Position
Assistant Professor
Latest degree
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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
I have not decided yet - the release schedule is still unknown
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available