Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparing single dose and double dose of Gonadotropin-releasing hormone (GNRH) agonist in endometriosis triggering undergoing assisted reproductive technology (ART) cyle

Protocol summary

Study aim

Comparing single dose and double dose of Gonadotropin releasing hormone agonist in endometriosis triggering undergoing Assisted reproductive technology

Design

80 patients with endometriosis under assisted reproductive therapy 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 S who receive single dose.

Settings and conduct

All procedures are performed by a surgeon in a Ḏena referral endometriosis hospital. 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 recombination Follicle stimulating hormone and Gonadotropin releasing hormone antagonist. Evaluation of follicles will be monitored by vaginal ultrasound. 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 receive double dose and the other one will receive single dose of GNRH agonists.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Definite diagnosis of endometriosis ,21-35 years. Exclusion criteria:History of uterine and ovary surgery,Polycystic ovary syndrome, Triggering with HCG,hypo gonadotrpic hypogonadism

Intervention groups

After performing the necessary tests and diagnostic ultrasound that meet the inclusion criteria will be randomly divided into two groups of D and S. After stimulating the follicles, we will trigger the group D with double dose and group S with single dose of GNRH agonists.

Main outcome variables

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: **IRCT20200925048836N3**
Registration date: **2022-10-21, 1401/07/29**
Registration timing: **prospective**

Last update: **2022-10-21, 1401/07/29**
Update count: **0**

Registration date

2022-10-21, 1401/07/29

Registrant information

Name

Elham Askary

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing single dose and double dose of Gonadotropin-releasing hormone (GNRH) agonist in endometriosis triggering undergoing assisted reproductive technology (ART) cyle

Public title

The effect 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 Assisted reproductive technology (ART) method Normal serum Follicle stimulating hormone (FSH) concentration in primary follicular phase Anti mullerian hormone (AMH) more than 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 Human chorionic gonadotropin (HCG) drug 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
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

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 (D̲), 3 (D), 4 (S), 5 (S),..... 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 S or D drug. 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 S 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

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Fars

Postal code

34786-71946

Approval date

2022-09-11, 1401/06/20

Ethics committee reference number

IR.SUMS.REC.1401.417

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N80.1

ICD-10 code description

Endometriosis of ovary

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 (D), 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 diphereline (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 (S), 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 diphereline (GNRH agonist). 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
Zahra Goudarzi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

Elham Askari

Position

Assitant

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

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

Title and more details about the data/document

Statistical Results

When the data will become available and for how long

6 month after the project completion

To whom data/document is available

By obtaining a license from the ethics committee and for scientific and research use in coordination with the main researchers

Under which criteria data/document could be used

The data is for use in this design only. If necessary, after obtaining the necessary permits from the ethics committee

From where data/document is obtainable

To researchers responsible for responding to this plan

What processes are involved for a request to access data/document

Written request Coordinated by the ethics committee 2 months

Comments