

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

clinical pregnancy will be determined and compared between the two groups.

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 receive double dose and the other one will receive 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 oocytes; fertilization and blastocyst conversion; ovarian hyperstimulation syndrome; implantation rate and

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)

Phone

+98 71 3233 2365

Email address

elliaskary_md@yahoo.com

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 triple 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, polycystic ovarian syndrome, triggering with HCG severe fertilizing disorder in spouse patient with hypogonadotropic 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/ranalloc.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 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 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 distributor 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

Street address

Dena hospital, Zargari blvd

City

shiraz

Province

Fars

Postal code

71867-64951

Phone

+98 71 3649 0411

Email

info@denahospital.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaianzadeh

Street address

Shiraz University of Medical Sciences, Zand St, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ ۷۱۳۴۸

Phone

+98 71 3230 5410

Email

rezaiana@sums.ac.ir

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

elliaskary_md@yahoo.com

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

07134814336

Phone

+98 71 3233 2365

Fax

+98 71 3233 2365

Email

elliaskary_md@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Askari Elham

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

07134814336

Phone

+98 71 3233 2365

Fax

+98 71 3233 2365

Email

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Askari Elham

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

07134814336

Phone

+98 71 3233 2365

Fax

+98 71 3233 2365

Email

elliaskary_md@yahoo.com

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