

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of dienogest, Oral contraceptive pill(OCP), Decapeptyl treatment, and fresh transfer method after ovum pickup in IVF women candidates on pregnancy outcomes in women with endometriosis

Protocol summary

Study aim

Determining the effect of dienogest, Oral contraceptive pill(OCP), Decapeptyl treatment, and fresh transfer method after ovum pickup in IVF candidate women on pregnancy outcomes

Design

A randomized, non-blinding clinical trial, with parallel groups, Phase 2 on 88 patients

Settings and conduct

In this randomized clinical trial study without blinding, 88 women candidates for IVF referring to Shahid Beheshti and Amin Hospitals of Isfahan will be included in the study and will be randomly divided into four groups. Then, each group is treated with dienogest, oral contraceptive pill(OCP), decapeptyl, and fresh transfer method, respectively. Then the percentage of HCG positivity and endometrial thickness of the patients will be evaluated and compared among the four groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include Infertile women of reproductive age 30-45 years, suffering from endometriosis, IVF candidate, and consent to participate in the study. Exclusion criteria include any drug sensitivity, having a history of thromboembolic diseases, malignancy, positive family history of thrombophilia, prohibition of pregnancy, and having infectious diseases.

Intervention groups

The first intervention group: Patients in this group were treated with dienogest at the rate of 2 mg/kg for 3 months, and then IVF was immediately performed on them. The second intervention group: Patients in this group were treated with oral contraceptive pills (OCP) for 3 months, and then IVF was immediately performed on them. The third intervention group: Patients in this group were treated with decapeptyl 3.75 mg for 3 months. Then 15 days after the last dose, IVF is performed on them. In the fourth intervention group: for patients in this

group without receiving the above three drugs, embryo fresh transfer is done.

Main outcome variables

HCG; Clinical pregnancy percentage; Endometrial thickness

General information

Reason for update

Acronym

IVF

IRCT registration information

IRCT registration number: **IRCT20220609055118N1**

Registration date: **2022-08-30, 1401/06/08**

Registration timing: **prospective**

Last update: **2022-08-30, 1401/06/08**

Update count: **0**

Registration date

2022-08-30, 1401/06/08

Registrant information

Name

Shadi Soroushfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3131 8818

Email address

shadisoroushfar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of dienogest, Oral contraceptive pill(OCP), Decapeptyl treatment, and fresh transfer method after ovum pickup in IVF women candidates on pregnancy outcomes in women with endometriosis

Public title
The effect of dienogest, Oral contraceptive pill(OCP), Decapeptyl treatment, and fresh transfer method on pregnancy outcomes in women with endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Infertile women Reproductive age 30-45 years Suffering from any of the stages 3 or 4 of endometriosis IVF candidate Consent to participate in the study
Exclusion criteria:
 Any drug sensitivity History of thromboembolic diseases, malignancy Positive family history for thrombophilia Contraindication of contraceptive use, GnRH agonist Prohibition of pregnancy Having infectious diseases such as hepatitis B, C or HIV

Age
From **30 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 88 eligible patients are randomly selected. For this, the letter A is written on 22 sheets, the letter B is written on 22 sheets, the letter C is written on 22 sheets, and the letter D is written on 22 sheets, and each of them is placed in an envelope. Then each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of three groups.

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 Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2021-11-20, 1400/08/29

Ethics committee reference number

IR.MUI.MED.REC.1400.643

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

Level of human chorionic gonadotropin (B-HCG)

Timepoint

After the intervention

Method of measurement

Urinalysis

2

Description

Endometrial thickness

Timepoint

Before and after the intervention

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: Patients in this group were treated with dienogest at the rate of 2 mg/kg for 3 months, and then IVF was immediately performed on them.

Category

Treatment - Drugs

2

Description

The second intervention group: Patients in this group were treated with oral contraceptive pills (OCP) for 3 months, and then IVF was immediately performed on them.

Category

Treatment - Drugs

3

Description

The third intervention group: patients in this group were treated with decapeptyl 3.75 mg for 3 months; So that they receive a dose of medicine every 28 days. Then 15 days after the last dose, IVF is performed on them.

Category

Treatment - Drugs

4

Description

Fourth intervention group: For patients in this group, without receiving the above three drugs, embryo transfer is done fresh.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Hatav Ghasemi Tehrani

Street address

Motahari Street.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3234 6338

Email

tehrani@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hatav Ghasemi Tehrani

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Al-Zahra Hospital, Sofeh Blvd., Tohid Street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

tehrani@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hatav Ghasemi Tehrani

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Al-Zahra Hospital, Sofeh Blvd., Tohid Street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

tehrani@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shadi Soroushfar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

6 floor, Nikan build, Al-khojand st. , Soroush ave.

City

Isfahan

Province

Isfahan

Postal code

813991111

Phone

+98 31 3131 8818

Fax

Email

Shadisoroushfar@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

There is no further information

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