

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of oral contraceptive with gonadotropin-releasing hormone (GnRH) agonist versus Estradiol Valerate on the pregnancy continuity after frozen embryo transfer in infertile women: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of oral contraceptive with gonadotropin-releasing hormone (GnRH) agonist versus Estradiol Valerate on the pregnancy continuity after a frozen embryo transfer in infertile women

Design

This is a double-blind randomized clinical trial, phase II, in which 100 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible infertile women referring to the Fatemeh Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 40 years, Infertile women candidate for the embryo transfer process, Having more than 3 embryos for transfer, Having a healthy uterine cavity, Having constant embryo culture medium, Having a constant embryo transfer environment, Having constant fetal quality, Having fixed embryology, Exclusion criteria: Being a smoker, Idiopathic infertility, Patients with donated oocytes,

Intervention groups

Intervention group: Oral contraceptive pill once daily from the second day of the menstrual cycle for 12 days plus a subcutaneous injection of GnRH agonist 0.5 mg daily from the 15th day of the menstrual cycle for 14 days Control group: Estradiol Valerate tablet (manufactured by Abureihan Pharmaceutical Co.) 6 mg twice a day from the second day of the menstrual cycle for at least 10 days

Main outcome variables

Primary outcome: Pregnancy continuity, Secondary outcome: Ectopic pregnancy, polygamous pregnancy, spontaneous abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N342**

Registration date: **2020-03-04, 1398/12/14**

Registration timing: **retrospective**

Last update: **2020-03-04, 1398/12/14**

Update count: **0**

Registration date

2020-03-04, 1398/12/14

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral contraceptive with gonadotropin-releasing hormone (GnRH) agonist versus Estradiol Valerate on the pregnancy continuity after frozen embryo transfer in infertile women: a double-blind randomized clinical trial

Public title

Effect of oral contraceptive with gonadotropin-releasing hormone (GnRH) agonist versus Estradiol Valerate on the pregnancy continuity after frozen embryo transfer in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 40 years, Infertile women candidate for the embryo transfer process, Having more than 3 embryos for transfer, Having a healthy uterine cavity, Having constant embryo culture medium, Having a constant embryo transfer environment, Having constant fetal quality, Having fixed embryology,

Exclusion criteria:

Being a smoker, Idiopathic infertility, Patients with donated oocytes,

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **128**

More than 1 sample in each individual

Number of samples in each individual: **64**

64 infertile women will be assigned to the intervention group and 64 to the control group.

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be

then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs will be given in coded envelopes. The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

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Postal code

6517838695

Approval date

2019-08-20, 1398/05/29

Ethics committee reference number

IR.UMSHA.REC.1398.337

Health conditions studied**1****Description of health condition studied**

Artificial fertilization

ICD-10 code

N98

ICD-10 code description

Complications associated with artificial fertilization

Primary outcomes**1****Description**

Pregnancy continuity after embryo transfer

Timepoint

12 weeks after the intervention
Method of measurement
With ultrasonography

Secondary outcomes

1

Description

Ectopic pregnancy

Timepoint

12 weeks after the intervention

Method of measurement

With ultrasonography

2

Description

Polygamous pregnancy

Timepoint

12 weeks after the intervention

Method of measurement

With ultrasonography

3

Description

Spontaneous abortion

Timepoint

12 weeks after the intervention

Method of measurement

With ultrasonography

Intervention groups

1

Description

Oral contraceptive pill once daily from the second day of the menstrual cycle for 12 days plus a subcutaneous injection of GnRH agonist 0.5 mg daily from the 15th day of the menstrual cycle for 14 days

Category

Treatment - Drugs

2

Description

Control group: Estradiol Valerate tablet (manufactured by Abureihan Pharmaceutical Co.) 6 mg twice a day from the second day of the menstrual cycle for at least 10 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Dr Fatemeh Jamshidi

Street address

Fatemieh Hospital, Pasdaran Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Fatemeh Jamshidi

Position

Resident of Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Jalal Poorolajal

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Professor of Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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