Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Fatemieh 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 form 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

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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
Hamadan
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Hamadan
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 form 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
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Sponsors / Funding sources

1

Sponsor
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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
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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