Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of ethinyl estradiol with sildenafil citrate versus ethinyl estradiol on endometrial thickness in infertile women: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of ethinyl estradiol with sildenafil citrate versus ethinyl estradiol on endometrial thickness in infertile women. Design: A randomized clinical trial. Setting and conduct: The eligible infertile women who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 40 years; male factor Infertility; no response to ovulation induction and intrauterine inoculation of semen. Exclusion criteria: Hydrosalpinx in one or both tubes; smoker; absence of at least two reached follicles following treatment; absence of fetus or at least one fetus. Intervention group: Vaginal ethinyl estradiol 5 mg 4 times a day plus vaginal sildenafil citrate 25 mg 4 times a day for 2 weeks. Control group: Vaginal ethinyl estradiol 5 mg 4 times a day for 2 weeks. Primary outcome: Assessing the endometrial thickness one and two weeks after treatment using transvaginal sonography. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not blinded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704119014N156**
Registration date: **2017-04-12, 1396/01/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-12, 1396/01/23

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-05-21, 1396/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of ethinyl estradiol with sildenafil citrate versus ethinyl estradiol on endometrial thickness in infertile women: a randomized clinical trial

Public title

Comparison of the effect of ethinyl estradiol with sildenafil citrate versus ethinyl estradiol on endometrial thickness in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 40 years; male factor Infertility; no response to ovulation induction and intrauterine inoculation of semen. Exclusion criteria: Hydrosalpinx in one or both tubes; smoker; absence of at least two reached follicles following treatment; absence of fetus or at least one fetus.

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

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not blinded.

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 the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2007-04-08, 1386/01/19

Ethics committee reference number
IR.UMSHA.REC.1396.35

Health conditions studied

1

Description of health condition studied
Female infertility

ICD-10 code
N97

ICD-10 code description
Female infertility

Primary outcomes

1

Description
Assessing the endometrial thickness

Timepoint
one and two weeks after treatment

Method of measurement
using transvaginal sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Vaginal ethinyl estradiol 5 mg 4 times a day plus vaginal sildenafil citrate 25 mg 4 times a day for 2 weeks.

Category
Treatment - Drugs

2

Description
Control group: Vaginal ethinyl estradiol 5 mg 4 times a day for 2 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemieh Hospital

Full name of responsible person
Dr Artimis Sadeghian

Street address
Fatemieh Hospital, Pasdaran Ave.

City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty