

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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 Fatemeh 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

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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

City

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****Contact****Name of organization / entity**

Fatemieh Hospital

Full name of responsible person

Dr Artimis Sadeghian

Position

Resident of Gynecology

Other areas of specialty/work**Street address**

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Postal code**Phone**

+98 81 3828 3939

Fax**Email**

art_sadeghian@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Fatemieh Hospital

Full name of responsible person

Dr Artimis Sadeghian

Position

Resident of Gynecology

Other areas of specialty/work**Street address**

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Postal code**Phone**

+98 81 3828 3939

Fax**Email**

art_sadeghian@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work**Street address**

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Fax**Email**

poorolajal@umsha.ac.ir

Web page address**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*