

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the effects of conjugated estrogen with vaginal sildenafil on endometrial diameter of patients treated by intracytoplasmic sperm injection(ICSI) admitting to Urmia Shahid Motahari and Mahzad Hospital

Protocol summary

Study aim

Comparison of uterine endometrial thickness between conjugated estrogen and sildenafil groups in patients with low endometrial thickness referred to Shahid Motahari and Mahzad hospitals in Urmia.

Design

Clinical trial with control group, open labeled, phase 3 on a sample of 30 patients.

Settings and conduct

Patients with endometrial preparation routine protocol of endometrial thickness less than 7 mm will be included in the study and will be divided into two groups. The intervention group will receive 2 mg of estradiol valerate 2 tablets as TDS plus vaginal sildenafil 50 mg as TDS and the control group will receive 2 mg of estradiol valerate 2 tablets as TDS plus conjugated estrogen 1.25 mg as BID. The study site will be MOTAHARI and MAHZAD hospitals in Urmia.

Participants/Inclusion and exclusion criteria

Inclusion criteria included patients undergoing IVF who did not conceive according to the standard uterine preparation protocol and having two frozen embryo or more. Exclusion criteria also include nitrate treated hypertension (HTN), cerebrovascular accident (CVA), thrombophilia, and use of nitrate-derived drugs.

Intervention groups

control: Continuation of 2 mg estradiol valerate(two tablets) TDS plus conjugated estrogen 1.25 mg BID from day 2 to day of embryo transfer. case: Continuation of 2 mg estradiol valerate (two tablets) TDS plus sildenafil 50 mg TDS from the day of endometrial thickness above 7 mm The start has begun to determine the BHCG response.

Main outcome variables

Revealing the effect of vaginal sildenafil on endometrial thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220314054278N1**

Registration date: **2022-05-03, 1401/02/13**

Registration timing: **registered_while_recruiting**

Last update: **2025-10-17, 1404/07/25**

Update count: **1**

Registration date

2022-05-03, 1401/02/13

Registrant information

Name

farnaz ettehadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3331 5198

Email address

farnazettehadi1989@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-16, 1400/12/25

Expected recruitment end date

2022-08-16, 1401/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of conjugated estrogen with vaginal sildenafil on endometrial diameter of patients treated by intracytoplasmic sperm injection(ICSI) admitting to Urmia Shahid Motahari and Mahzad Hospital

Public title

Comparison of the effects of conjugated estrogen with vaginal sildenafil on endometrial diameter

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Patients undergoing IVF who did not conceive according to the standard uterine preparation protocol
2. Having two frozen embryos or more

Exclusion criteria:

Hypertension(HTN) treated with nitrates Cerebrovascular accident(CVA) Thrombophilia Using drugs with nitrate derivatives

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia university of medical sciences

Street address

End of emergency alley, Resalat Blvd, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2022-03-02, 1400/12/11

Ethics committee reference number

IR.UMSU.REC.1400.470

Health conditions studied

1

Description of health condition studied

Influence of different factors on endometrial thickness

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Endometrial Thickness

Timepoint

Day 14 of the menstrual cycle at the time of routine endometrial preparation protocol and after receiving vaginal sildenafil as TDS with 2 mg estradiol valerate as TDS.

Method of measurement

Sonography

Secondary outcomes

1

Description

Gravidity

Timepoint

At the beginning of study

Method of measurement

Oral question

2

Description

Chemical pregnancy rate

Timepoint

After performing the intervention on the study groups

Method of measurement

B-HCG serum level measurement

3

Description

Abortion

Timepoint

Clinical symptoms in favor of loss of pregnancy products

Method of measurement

Sonography and Clinical exam based

Intervention groups

1

Description

Intervention group: Patients receiving Estradiol Valerate 2 mg(Brand name: Abu Reihan estradiol valerate, Abu Reihan pharmaceuticals) 2 tablets TDS plus vaginal sildenafil 50 mg(Brand name: Viagra, Pfizer company) TDS

Category

Treatment - Drugs

2

Description

Control group: Patients receiving estradiol valerate 2 mg(Brand name: Abu Reihan estradiol valerate, Abu Reihan pharmaceuticals) 2 tablets TDS plus conjugated estrogen 1.25 mg(Brand name: Estromarin, Abu Reihan pharmaceuticals) BID from day 2 of cycle to day of embryo transfer

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Shahid Motahari hospital

Full name of responsible person

Farnaz Ettehadi

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Ayatollah Kashani street, Urmia

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2

Recruitment center

Name of recruitment center

Urmia Mahzad hospital

Full name of responsible person

Farnaz Ettehadi

Street address

Hasani sreet, Urmia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saber Gholizadeh

Street address

Emergency alley, Resalat Blvd, Urmia

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Email

academic.relations@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Farnaz Ettehdi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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No17, Sogol alley, North Shahriar Ave, Valiasr, Tabriz

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Position

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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