

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of Sildenafil and estradiol valerate on increasing endometrial thickness before intra uterine insemination

#### Protocol summary

##### Study aim

Determining the effect of Sildenafil and estradiol valerate on increasing endometrial thickness before intra uterine insemination

##### Design

A randomized, single blinded, controlled clinical trial with a parallel group design of 100 patients. Randomisation was carried out by Rand function of Microsoft Excel software

##### Settings and conduct

Patients referred to Alavi hospital of Ardabil with infertility due to decreased endometrial thickness are enrolled in to one of the 2 groups of this study . Patients will be randomly assigned to one of the groups and will be evaluated for treatment. Patients endometrial thickness will be evaluated by vaginal ultrasound after 9 days.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with infertility due to a decreased endometrial thickness 2. Age between 20 to 35 years old 3. BMI lower than 30 kg per square meters  
Exclusion criteria: 1. Women with congenital uterine abnormality or acquired deformity of uterine tube which interferes with implantation 2. Women with tubal infertility 3. Women with contraindication to estrogen therapy (CVA or DVT history and benign hepatic diseases) 4. Women which have a male factor infertility (Aospermia , Teratospermia, ...)

##### Intervention groups

Intervention group: An Estradiol valerate tablet every 12 hours from the 10th day of menstruation to the initiation of ovulation(10 days)+ Viagra vaginal gel 25 mg daily from day 9 to day 12  
Control group: An Estradiol valerate tablet every 12 hours from the 10th day of menstruation to the initiation of ovulation(10 days)+ Placebo gel from days 9 to day 12

##### Main outcome variables

Endometrial thickness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210313050688N1**

Registration date: **2021-05-17, 1400/02/27**

Registration timing: **prospective**

Last update: **2021-05-17, 1400/02/27**

Update count: **0**

##### Registration date

2021-05-17, 1400/02/27

##### Registrant information

##### Name

Faranak jalilvand

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3323 1206

##### Email address

f.jalilvand@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-22, 1400/03/01

##### Expected recruitment end date

2021-11-21, 1400/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Sildenafil and estradiol valerate on increasing endometrial thickness before intra uterine insemination

#### Public title

Effect of Sildenafil and estradiol valerate on increasing endometrial thickness

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with infertility due to a decreased endometrial thickness Age between 20 to 35 years old BMI lower than 30 kg per square meters

##### Exclusion criteria:

Women with congenital uterine abnormality or acquired deformity of uterine tube which interferes with implantation Women with tubal infertility Women with contraindication to estrogen therapy (CVA or DVT history and benign hepatic diseases) Women which have a male factor infertility (Aospermia , Teratospermia, ...)

#### Age

From **20 years** old to **35 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients will be enrolled randomly in to one of the groups based on inclusion criteria. Randomisation sequence will be processed by Microsoft Excel program via (RANDBETWEEN) command and numbers 0 and 1 will be allocated to each group to choose the group of the subject.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Viagra and placebo tablets are indistinguishable for patients and can not be recognised by their appearance

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

#### Street address

Deputy of research and technology, Northern side of Ardabil university of medical sciences, Daneshgah sq., Daneshgah st

#### City

Ardabil

#### Province

Ardabil

#### Postal code

5618985991

#### Approval date

2020-12-07, 1399/09/17

#### Ethics committee reference number

IR.ARUMS.REC.1399.571

### Health conditions studied

#### 1

##### Description of health condition studied

Female infertility due to nonimplantation of ovum

##### ICD-10 code

N97.2

##### ICD-10 code description

Female infertility of uterine origin

### Primary outcomes

#### 1

##### Description

Endometrial thickness

##### Timepoint

Based on the reported sonographic result 9 days after initiation of treatment

##### Method of measurement

Transvaginal Ultrasound

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Control group: Patients of this group will receive An Estradiol valerate tablet every 12 hours from the 10th day of menstruation to the initiation of ovulation(10days) and also, they will receive Placebo gel vaginally from days 9 to 12 of the menstruation (up to 4 days). To evaluate endometrial thickness, patients will undergo vaginal sonography before initiation of treatment and 9 days after the treatment is completed.

##### Category

Placebo

## 2

### Description

Intervention group: Patients of this group will receive An Estradiol valerate tablet every 12 hours from the 10th day of menstruation to the initiation of ovulation(10days) and also, they will receive Viagra gel vaginally from days 9 to 12 of the menstruation (up to 4 days). To evaluate endometrial thickness, patients will undergo vaginal sonography before initiation of treatment and 9 days after the treatment is completed.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alavi hospital

##### Full name of responsible person

Dr Faranak Jalilvand

##### Street address

Maadi street, Saheli street

##### City

Ardabil

##### Province

Ardabil

##### Postal code

5613974156

##### Phone

+98 45 3323 1206

##### Email

alavi@arums.ac.ir

##### Web page address

<https://www.arums.ac.ir/alavi/fa>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ardabil University of Medical Sciences

##### Full name of responsible person

Dr Farhad Pourfarzi

##### Street address

Deputy of research and technology, Northern side of Ardabil university of medical sciences, Daneshgah sq., Daneshgah st

##### City

Ardabil

##### Province

Ardabil

##### Postal code

5618985991

##### Phone

+98 45 3353 4776

##### Email

research@arums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

##### Full name of responsible person

Dr Faranak Jalilvand

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Alavi hospital, Maadi st., Saheli st.

##### City

Ardabil

##### Province

Ardabil

##### Postal code

5613974156

##### Phone

+98 45 3324 8888

##### Email

f.jalilvand@arums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ardabil University of Medical Sciences

##### Full name of responsible person

Dr Faranak Jalilvand

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Alavi hospital, Maadi st., Saheli st.

##### City

Ardabil

**Province**

Ardabil

**Postal code**

5613974156

**Phone**

+98 45 3324 8888

**Email**

f.jalilvand@arums.ac.ir

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

Ardabil University of Medical Sciences

**Full name of responsible person**

Dr Faranak Jalilvand

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Alavi hospital, Maadi st., Saheli st.

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5613974156

**Phone**

+98 914 420 5288

**Email**

f.jalilvand@arums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Only data related to outcomes will be shared

**When the data will become available and for how long**

Data will be accessible from 21 march 2022 onward

**To whom data/document is available**

Data will be accessible from 21 march 2021 onward

**Under which criteria data/document could be used**

No restrictions on data analysis after data is shared

**From where data/document is obtainable**

Dr Faranak Jalilvand

**What processes are involved for a request to access data/document**

All requests should be sent to the email address f.jalilvand@arums.ac.ir and will be responded in 2 weeks time

**Comments**