Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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 groupsand 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 wich 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 wich 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 wich interferes with implantation Women with tubal infertility Women with contraindication to estrogen therapy (CVA or DVT history and benign hepatic diseases) Women wich 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

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

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5618985991

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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

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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

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Subspecialist

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Person responsible for updating data

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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 wil 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