

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of vaginal sildenafil on endometrial thickness and pregnancy rates in infertile women undergoing intrauterine insemination

Protocol summary

Study aim

Evaluation of the effect of vaginal sildenafil on endometrial thickness and fertility in infertile women IUI candidates referred to infertility clinic of Shahid Beheshti Hospital in Kashan in 2020

Design

Clinical trial with control group, with parallel, randomized, phase 3 groups on 60 patients. The card shuffle method was used for randomization.

Settings and conduct

This clinical trial study will be performed on 60 infertile women IUI candidates referred to the infertility clinic of Shahid Beheshti Hospital in 2016.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All women under the age of 40 are candidates for IUI for the first time up to the third maximum, with a sperm count of 10-10 million, a motility of 25-30%, a normal morphology of 3-4%, and a BMI of less than 40. Exclusion criteria: Hypotension, history of endocrine diseases, history of stroke or heart attack, cardiovascular, renal and hepatic problems, use of nitrites or nitrates

Intervention groups

The subjects were randomly divided into two groups of 30 people receiving sildenafil and estradiol (experimental group) and the group receiving estradiol (control group). In the experimental group, a 25 mg sildenafil vaginal tablet and an oral estradiol 2 mg tablet are administered every 12 hours every 12 hours, and in the control group, a 2 mg estradiol tablet is administered every 12 hours until the day of injection, and the endometrial thickness is repeated daily. IUI is measured. Two weeks after IUI, a pregnancy test will be done with a Beta HCG blood test.

Main outcome variables

Endometrial thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210110049997N1**
Registration date: **2021-06-04, 1400/03/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-04, 1400/03/14**

Update count: **0**

Registration date

2021-06-04, 1400/03/14

Registrant information

Name

niloofar mehry

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

niloofar.mehry.1988@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-16, 1399/12/26

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vaginal sildenafil on endometrial thickness and pregnancy rates in infertile women undergoing intrauterine insemination

Public title

The effect of vaginal sildenafil on endometrial thickness and pregnancy rates in infertile women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The number of sperm in female spouses is between 5-10 million. Sperm motility of female spouses should be between 25-30%. The normal morphology of female spouses sperm is between 3-4%. Women's body mass index should be less than 40. Endometrial thickness less than 7 mm.

Exclusion criteria:

Hypotension History of endocrine diseases History of stroke or heart attack Cardiovascular problems Consumption of nitrites or nitrates

Age

To 40 years old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects were randomly divided into two groups of 30 people receiving sildenafil and estradiol (experimental group) and the group receiving estradiol (control group). In this method, a number of cards selected by the researcher as the first group and the same number of cards for the next groups are considered; Then, by merging the cards together (flipping the cards), a card is taken out and its allocation is recorded, and that card is returned to the other cards after being taken out. The cards are then merged again and another card is removed. This process continues until a random sequence according to the sample size is reached.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Faculty of Medicine and Dentistry - Kashan University

of Medical Sciences

Street address

Kashan-Qutb Ravandi Boulevard-Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8715973474

Approval date

2020-09-08, 1399/06/18

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.101

Health conditions studied**1****Description of health condition studied**

Female infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes**1****Description**

Endometrial thickness

Timepoint

Measurement of endometrial thickness at the beginning of the study (before the start of the intervention, which should be less than 7 mm) and 14 days after the start of taking an oral estradiol tablet and a sildenafil vaginal tablet

Method of measurement

Ultrasound device

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Sildenafil and estradiol, made in Iran and Marham Daroo Company, a vaginal tablet of sildenafil 25 mg and an oral tablet of estradiol 2 mg every 12 hours are prescribed every 6 hours.

Category

Treatment - Drugs

2**Description**

Control group: Estradiol 2 mg tablets are given every 12 hours until the day of HCG (human chorionic

gonadotropin) injection.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Kashan

Full name of responsible person

Research Assistant

Street address

Qutb Ravandi Blvd., Parstar Blvd., Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8715973474

Phone

+98 31 5550 0111

Email

ResearchAssistant@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zohre Tabasi

Street address

Qutb Ravandi Blvd., Parstar Blvd., Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8715973474

Phone

+98 31 5544 3022

Email

drtabasiz@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Niloofer Mehry

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 32, 24 metri taro pood alley, elahie Blvd, Kashan Town

City

Kashan

Province

Isfahan

Postal code

8719860004

Phone

+98 31 5554 0026

Fax

Email

niloofer.mehry.1988@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Niloofer Mehry

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 32, 24 metri taro pood alley, elahie Blvd, Kashan Town

City

Kashan

Province

Isfahan

Postal code

8719860004

Phone

+98 31 5554 0026

Fax

Email

niloofer.mehry.1988@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Niloofer Mehry

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 32, 24 metri taro pood alley, elahie Blvd, Kashan
Town

City

Kashan

Province

Isfahan

Postal code

8719860004

Phone

+98 31 5554 0026

Fax**Email**

niloofar.mehry.1988@gmail.com

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

Not applicable

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

Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long

Access period starts from 1400

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Request in writing and signed by mail

From where data/document is obtainable

Mainly responsible for the study

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

Request and provide information

Comments