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
Isfehan
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
Isfehan

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
Isfehan

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
Niloofar 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
Isfehan

Postal code
8719860004

Phone
+98 31 5554 0026

Fax

Email
niloofar.mehry.1988@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Niloofar Mehry

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Resident

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Person responsible for updating data

Contact

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Kashan University of Medical Sciences

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Phone
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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