

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative effect of oral and vaginal sildenafil on endometrial thickness in infertile women with thin endometrium in frozen embryo transfer cycles

Protocol summary

Study aim

Determining the comparative effect of vaginal and oral administration of sildenafil on endometrial thickness in infertile women with thin endometrium in frozen embryo transfer cycles

Design

Randomized clinical trial will perform on 3 groups of infertile women, including a control group receiving sildenafil citrate only and two study groups receiving oral and vaginal sildenafil citrate. .

Settings and conduct

This study is about the treatment of female infertility and will perform double-blind at the Umm Al-Banin Infertility Treatment Center of Ganjavian Hospital. The study is a case-control study and will perform on 3 groups of infertile women of childbearing age. The control group is only sildenafil and The case group received sildenafil vaginally and orally.

Participants/Inclusion and exclusion criteria

Entry requirements: all patients will be contain Infertile women in the age range of 39-18 years All women who have a frozen fetus and have been a history of a thin endometrium with routine medication preparation for endometriosis. The condition of the fetus returned from the freezer should be of good quality (grade A, B) Lack of drug sensitivity No entry conditions: History of endocrine disease: Diabetes, Hyperthyroidism, Hyperprolactinemia

Intervention groups

72 Infertile women were divided into three groups based on a random table and to prepare the endometrium, the first group would be given oral estradiol and the second and third groups, in addition to the estradiol treatment protocol, would be given oral and vaginal sildenafil citrate tablets, respectively. In all three groups, clinical monitoring will be performed serially every other day from the 11th day of menstruation to measure endometrial thickness.

Main outcome variables

amount of endometrial thickness, clinical pregnancy, chemical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210216050385N1**

Registration date: **2021-11-13, 1400/08/22**

Registration timing: **prospective**

Last update: **2021-11-13, 1400/08/22**

Update count: **0**

Registration date

2021-11-13, 1400/08/22

Registrant information

Name

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of oral and vaginal sildenafil on endometrial thickness in infertile women with thin endometrium in frozen embryo transfer cycles

Public title

effect of sildenafil citrat on endometrial thickness

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infertile women between 39-18 years All women who have a frozen fetus and have a history of a thin endometrium routinely prescribed medication to prepare the endometrium The condition of the fetus returned from the freez should be have a good quality (grade A-B) Lack of drug sensitivity

Exclusion criteria:

History of endocrine disease: Diabetes - Hyperthyroidism - Hyperprolactinemia History of hysteroscopic surgery due to intrauterine adhesions specific cardiovascular disease History of stroke or myocardial infarction serious hapeatofailure or renal failure Alcohol abuse or substance abuse Use of donated ovum PCOS endometriosis

Age

From **18 years** old to **39 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

In this double-blind study, sick people, ie infertile women, will be unaware of how the study groups are divided into two groups receiving placebo and the main drug, and also those who will perform the intervention in the clinic, ie researchers will be unaware from the distribution of study groups receiving placebo and The main drug

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of dezful university of medical sciences

Street address

Headquarters of Dezful University of Medical Sciences and Health Services, Corner of Justice Street., Post St., 15 Khordad Blvd., Dezful

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Khouzestan

Postal code

6461665145

Approval date

2021-04-03, 1400/01/14

Ethics committee reference number

IR.DUMS.REC.1400.007

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

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

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

clinical pregnancy

Timepoint

Three to four weeks after embryo transfer

Method of measurement

Presence of pregnancy sac in vaginal ultrasonography

2**Description**

chemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

serologic labratory result BHCG≥25

3**Description**

endometrial thickness

Timepoint

From the eleventh day of the menstrual cycle serially every other day

Method of measurement

vaginal ultrasonography

Secondary outcomes**1****Description**

Transmitted fetal quality

Timepoint

transmission day

Method of measurement

In terms of quality, it is divided into one of 3 groups A, B and C based on the number and size of embryonic cells (blastomers), increasing the pervasiveness and presence of multinucleated cells.

2**Description**

implantation rate

Timepoint

Two weeks after embryo transfer

Method of measurement

beta-HCG examination

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

Intervention groupe 1: The second group, in addition to the estradiol treatment protocol, will be given oral sildenafil citrate tablets. Then, in the next stage of progesterone injection, 100 mg intramuscular for three to four days.

Category

Treatment - Drugs

2**Description**

Intervention groupe 2: In the third group, in addition to the estradiol treatment protocol, sildenafil citrate tablets will be given to the vagina. Due to the unavailability of vaginal sildenafil, the patient is asked to moisten the oral sildenafil citrate tablet and place it in the vagina. 100 mg intramuscular for four days

Category

Treatment - Drugs

3**Description**

Control groupe 1: The first group will receives only oral estradiol 3 times a day and then in the next stage of progesterone injection for three to four days at a rate of 100 mg intramuscular

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ganjavian Hospital, Dezful, Umm Al-Banin Infertility Center

Full name of responsible person

Sima jannati

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Dezful-Andimeshk highway, Dezful, Khuzestan province

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Dezfoul 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

fellowship

Latest degree

Specialist

Other areas of specialty/work

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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