

# 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

Mahdi Mohammadi nazar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 4235 8220

##### Email address

mahdinazari76@yahoo.com

##### 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

**City**

dezful

**Province**

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 $\geq$ 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

**Street address**

Dezful-Andimeshk highway, Dezful, Khuzestan province

**City**

Dezful

**Province**

Khuzestan

**Postal code**

1111111111

**Phone**

+98 61 4242 2040

**Email**

mahdinazari76@yahoo.com

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

Dezfoul University of Medical Sciences

**Full name of responsible person**

Dr.Sima jannati

**Street address**

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

**City**

dezful

**Province**

Khuzestan

**Postal code**

6461665145

**Phone**

+98 61 4242 8717

**Email**

info@Dums.ac.ir

**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

**Phone**

+98 61 4242 8203

**Email**

majidipour.n@dums.ac.ir

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

Dezfoul University of Medical Sciences

**Full name of responsible person**

Dr.Sima jannati

**Position**

fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

corner of 15 Khordad Boulevard, Post Street

**City**

Dezful

**Province**

Khouzestan

**Postal code**

6478135860

**Phone**

+98 61 4235 8110

**Email**

sjanati@ymail.com

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

Dezfoul University of Medical Sciences

**Full name of responsible person**

Mahdi Mohammadiazar

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 7, Mehr ST., Bahram town, Shush-e daniel,

**City**

shush

**Province**

Khouzestan

**Postal code**

6478135860

**Phone**

+98 61 4237 6455

**Email**

mahdinazari76@yahoo.com

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

Dezfoul University of Medical Sciences

**Full name of responsible person**

Narges Majidipour

**Position**

instructure

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Corner of Justice Street, 15 Khordad Blvd., Post St.

**City**

Dezful

**Province**

Khouzestan

**Postal code**

6461665145

**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