

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of sildenafil citrate on endometrial preparation and on the outcome of the frozen-thawed embryo transfer cycles in infertile women: a clinical trial

Protocol summary

Summary

Purpose: The aim of this study is to estimate the effect of sildenafil on endometrial thickness, endometrial pattern, and investigate estrogen level on the day of progesterone administration, the implantation rate and chemical pregnancy rate in frozen embryo transfer cycles. Methods: 80 women younger than 40 years who had high quality frozen embryos with history of poor endometrial response were included in the study and based on random allocation are divided in two groups. For group I (n=40) start 2mg estradiol valerat (tablet) from first to 4th day of the menstrual cycle, and continue by 4mg from 5th to 8th day, and 6mg from 9th to 20th day of the menstrual cycle. In the second group (n=40) in addition to the above treatment protocol, from first day of cycle until the day of starting progesterone will be given 50mg sildenafil citrate tablets daily and it was discontinued from 48 to 72 hr prior to the embryo transfer. In 13th day of the menstrual cycle endometrial thickness measured with transvaginal ultrasonography (arranged in a series every other day). Evaluations were performed by a single investigator. If the endometrial thickness is more than 8mm, 100 mg progesterone injected intramuscular and blood estrogen, progesterone level are measured then after three days embryo was transferred. Outcomes: Estradiol valerat and progesterone continued until two weeks after embryo transferred, then BHCG tested. If BHCG is positive, estradiol valerat and progesterone continues until 11 weeks of pregnancy. Then four weeks after the embryo transfer, the number of gestational sac are determined by vaginal ultrasound.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210232575N3**

Registration date: **2012-12-24, 1391/10/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-24, 1391/10/04

Registrant information

Name

Razieh Dehghani Firouzabadi

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University of Medical Sciences,
Vice chancellor for research

Expected recruitment start date

2009-03-20, 1387/12/30

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of sildenafil citrate on endometrial preparation and on the outcome of the frozen-thawed embryo transfer cycles in infertile women: a clinical trial

Public title

Effect of sildenafil citrate on endometrial preparation and on the outcome of the frozen-thawed embryo transfer cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All infertile women have high quality frozen embryos. Exclusion criteria: 1. Age > 40 2. History of endocrine disease such as: diabetes; Hyperthyroidism and Hyperprolactinemia 3. History of hysteroscopic surgery due to intrauterine adhesions 4. History of cardiovascular, renal or liver disease 5. Hypotension (blood pressure < 90/50) 6. History of stroke or myocardial infarction 7. Poor quality embryos 8. Alcohol or Substance abuse

Age

From **15 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Research and Clinical Center for Infertility, Yazd Shahid Sadoughi University of Medical Sciences

Street address

Bouali Ave., Safaeih, Research and Clinical Center for Infertility, Yazd, Iran.

City

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Postal code

8916877391

Approval date

2011-03-10, 1389/12/19

Ethics committee reference number

3428

2

Ethics committee

Name of ethics committee

Ethics Committee of Research and Clinical Center for Infertility, Yazd Shahid Sadoughi University o

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Approval date

2011-05-22, 1390/03/01

Ethics committee reference number

647

Health conditions studied

1

Description of health condition studied

Female Infertility

ICD-10 code

N98.3

ICD-10 code description

Complications of attempted introduction of embryo in embryo transfer

Primary outcomes

1

Description

Endometrial thickness

Timepoint

Within a day from 13th day of the menstrual cycle

Method of measurement

Vaginal sonography

2

Description

Chemical pregnancy

Timepoint

Two weeks after embryo transfer

Method of measurement

BHCG test

Secondary outcomes

1

Description

Duration of infertility

Timepoint

Before intervention

Method of measurement

Patient's medical record

2**Description**

Implantation rate

Timepoint

Four weeks after the embryo transfer

Method of measurement

Number of gestational sac are determined by vaginal ultrasound

3**Description**

FSH, LH, FSH/LH level

Timepoint

ratio in progesterone day administration

Method of measurement

Blood sample

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

For group I start 2mg estradiol valerat (tablet) from first to 4th day of the menstrual cycle, and continue by 4mg from 5th to 8th day, and 6mg from 9th to 20th day of the menstrual cycle. In 13th day of the menstrual cycle endometrial thickness estimated with transvaginal ultrasonography (arranged in a series every other day), evaluations were performed by a single investigator, if the endometrial thickness is more than 8mm, 100 mg progesterone injected intramuscular and after three days embryo was transferred. Estradiol valerat and progesterone continued until two weeks after embryo transferred, then BHCG tested. If BHCG is positive, estradiol valerat and progesterone continues until 11 weeks of pregnancy . Then four weeks after the embryo transfer, the number of gestational sac are determined by vaginal ultrasound.

Category

Treatment - Drugs

2**Description**

In the group II in addition to the above treatment protocol, from first day of cycle until the day of starting progesterone will be given 50mg sildenafil citrate tablets daily and it was discontinued between 48-72 hours previous of the embryo transfer. In 13th day of the menstrual cycle endometrial thickness estimated with transvaginal ultrasonography (arranged in a series every other day), evaluations were performed by a single investigator, if the endometrial thickness is more than 8mm, 100 mg progesterone injected intramuscular and after three days embryo was transferred. Estradiol valerat and progesterone continued until two weeks after embryo transferred, then BHCG tested. If BHCG is positive, estradiol valerat and progesterone continues

until 11 weeks of pregnancy . Then four weeks after the embryo transfer, the number of gestational sac are determined by vaginal ultrasound.

Category

Treatment - Drugs

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

Yazd Research and Clinical Center for Infertility

Full name of responsible person

Dr. Razeih Dehghani Firouzabadi

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Research and Clinical Center for Infertility, Bouali Ave., Safaeih, Yazd, Iran.

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

Yazd Shahid Sadoughi University of Medical Sciences and Health Services, Vice Chancellor for resear

Full name of responsible person

Dr. Fatemeh Ezaddini

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Bahonar SQ., Vice Chancellor for Research Office, Yazd Shahid Sadoughi University of Medical Sciences and Health Services, Yazd, Iran.

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Yazd

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

Yes

Title of funding source

Yazd Shahid Sadoughi University of Medical Sciences and Health Services, Vice Chancellor for resear

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Yazd Research and Clinical Center for Infertility,

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

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Position

Gynecologist

Other areas of specialty/work

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Dr. Razieh Dehghani Firouzabadi

Position

Gynecologist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty