

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The Survey of oral Sildenafil citrate and placebo effects on semen parameters in patients with idiopathic infertility

Protocol summary

Summary

In this double-blind randomized crossover clinical trial with a control group, the effects of sildenafil citrate on semen parameters will be examined in 84 patients 25 to 40 years old, with idiopathic infertility and normal erectile function referred to the Urology Clinic of Razi Hospital, Infertility Clinic of Al-Zahra Hospital and two private urology clinics in Rasht. First, a semen sample will be taken from all eligible persons. They will be asked not have to ejaculation 3 days before drug use and avoid smoking and caffeine use. And then by using the method of block randomization they will be randomized into one of the two groups of sildenafil citrate 50 mg and placebo recipients. Neither the participants nor the observers (researchers) know who will be placed in which group. One hour after treatment in both groups semen analysis again will be tested. After a washout period and spending the appropriate time for the next test which is defined one week, the two groups will be exchanged and semen analysis for the third time will be done one hour after taking the medicine. In this way during the study period all participants will receive once sildenafil citrate and once placebo. Volume, acidity (pH), liquefaction, viscosity and appearance of each samples and concentration, count, vitality, motility and morphology of sperm will be evaluated along with demographic information and other clinical and laboratory data of patients will be collected in the questionnaire which is developed by researchers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611291853N12**

Registration date: **2017-02-10, 1395/11/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Siavash Falahatkar

Name of organization / entity

Urology Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 3352 5259

Email address

urc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Urology Research Center, Guilan University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Survey of oral Sildenafil citrate and placebo effects on semen parameters in patients with idiopathic infertility

Public title

The effects of oral Sildenafil citrate on semen parameters

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Age range 25 to 40 years; normal erectile function; no history of acute febrile disease; no history of related drug use within 3 months before study
Exclusion criteria: Any factor that causes the testicles to get in contact with high temperatures includes long hot bath, sauna, bakery and other high-risk jobs; people with a history of seasonal allergies and sensitivities; consumption of alcohol, cocaine and certain medications, such as cimetidine, spironolactone, erythromycin, corticosteroids and methylxanthines such as theophylline, pentoxifylline and aminophylline and especially nitrates; history of testicular trauma or surgery; cardiovascular disease or high blood pressure and/or diabetes mellitus; consumption of hypertension drugs; consumption of drugs for the treatment of infertility

Age

From **25 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Randomization has been done by blocking or random block method in this study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Opposite Sepah Bank, Western Shahid Beheshti Blvd., Gaz Square

City

Rasht

Postal code

41938-93345

Approval date

2015-07-10, 1394/04/19

Ethics committee reference number

IR.GUMS.REC.1394.79

Health conditions studied

1

Description of health condition studied

Idiopathic infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

2

Description of health condition studied

Erectile Dysfunction

ICD-10 code

F52.2

ICD-10 code description

Failure of genital response

Primary outcomes

1

Description

Ejaculation Volume

Timepoint

Before intervention and 3 days later, one hour after taking the drug or placebo and again a week later with an interval of one hour after drug or placebo (in general, it will be measured 3 times)

Method of measurement

Semen analysis

2

Description

Sperm Concentration

Timepoint

Before intervention and 3 days later, one hour after taking the drug or placebo and again a week later with an interval of one hour after drug or placebo (in general, it will be measured 3 times)

Method of measurement

Semen analysis

3

Description

Sperm Count

Timepoint

Before intervention and 3 days later, one hour after taking the drug or placebo and again a week later with an interval of one hour after drug or placebo (in general, it will be measured 3 times)

Method of measurement

Semen analysis

4

Description

Sperm Motility

Timepoint

Before intervention and 3 days later, one hour after taking the drug or placebo and again a week later with an interval of one hour after drug or placebo (in general, it will be measured 3 times)

Method of measurement

Semen analysis

5

Description

Sperm Vitality

Timepoint

Before intervention and 3 days later, one hour after taking the drug or placebo and again a week later with an interval of one hour after drug or placebo (in general, it will be measured 3 times)

Method of measurement

Semen analysis

6

Description

Sperm Morphology

Timepoint

Before intervention and 3 days later, one hour after taking the drug or placebo and again a week later with an interval of one hour after drug or placebo (in general, it will be measured 3 times)

Method of measurement

Semen analysis

Secondary outcomes

1

Description

Sperm forward progression

Timepoint

Before intervention and 3 days later, one hour after taking the drug or placebo and again a week later with an interval of one hour after drug or placebo (in general, it will be measured 3 times)

Method of measurement

Semen analysis

2

Description

Appearance of Semen

Timepoint

Before intervention and 3 days later, one hour after taking the drug or placebo and again a week later with an interval of one hour after drug or placebo (in general, it will be measured 3 times)

Method of measurement

Semen analysis

3

Description

Sperm pH

Timepoint

Before intervention and 3 days later, one hour after taking the drug or placebo and again a week later with an interval of one hour after drug or placebo (in general, it will be measured 3 times)

Method of measurement

Semen analysis

4

Description

Semen viscosity

Timepoint

Before intervention and 3 days later, one hour after taking the drug or placebo and again a week later with an interval of one hour after drug or placebo (in general, it will be measured 3 times)

Method of measurement

Semen analysis

5

Description

Liquefaction

Timepoint

Before intervention and 3 days later, one hour after taking the drug or placebo and again a week later with an interval of one hour after drug or placebo (in general, it will be measured 3 times)

Method of measurement

Semen analysis

Intervention groups

1

Description

Intervention group: Sildenafil citrate 50 mg tablet, one dose, made in Iran

Category

Treatment - Drugs

2

Description

Control group: Placebo 50 mg tablet, one dose, made in Iran

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Soheil Kiyanfar (Resident of Urology)

Street address

Sardar Jangal Street, Razi Hospital

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

Head of Urology Research Centre, Dr. Siavsh Falahatkar

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Grant name

10506

Grant code / Reference number

32

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

Yes

Title of funding source

Urology Research Centre, Guilan University of Medical Sciences

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**

Urology Research Center, Guilan University of Medical Sciences

Full name of responsible person

Dr. Soheil Kiyanfar

Position

Co worker/Resident of Urology

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Full name of responsible person

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Position

Associated Proffesor of Guilan University of Medical Sciences

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Full name of responsible person

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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