# 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
**City**
Rasht

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Urology Research Centre, Guilan University of Medical Sciences
**Full name of responsible person**
Head of Urology Research Centre, Dr. Siavsh Falahatkar
**Street address**
Sardar Jangal Street, Razi hospital, Urology Research Centre
**City**
Rasht
**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
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

**Contact**
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Urology Research Center, Guilan University of Medical Sciences
**Full name of responsible person**
Dr. Gholamreza Mokhtari
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Associated Proffesor of Guilan University of Medical Sciences
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## Person responsible for updating data

**Contact**
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Urology Research Center, Guilan University of Medical Sciences
**Full name of responsible person**
Samaneh Esmaeili
**Position**
Research Expert/Master
**Other areas of specialty/work**
**Street address**
Urology Research Center, Razi Hospital, Sardar Jangal Street
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urc1384@yahoo.com
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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*