

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the therapeutic effect of topical sildenafil gel and oral sildenafil pill in patients with erectile dysfunction

Protocol summary

Study aim

1- Evaluation of the effect of sildenafil gel on the improvement of erectile dysfunction before and after treatment 2- Evaluation of the effect of sildenafil tablets on the improvement of erectile dysfunction before and after treatment 3- Evaluation of the effect of platelets and tablets on the improvement of erectile dysfunction before and after treatment

Design

Three groups: placebo-sildenafil gel, placebo-gel, sildenafil gel, placebo-placebo gel Block randomization Blind randomized clinical trial

Settings and conduct

In the present study, the physician and the drug provider will not be aware of the type of treatment and the group of patients. All patients will receive tablets and gels that have the same appearance and are not aware of the treatment group. setting : Urology clinic of Ali Ebn Abitaleb Hospital in Zahedan

Participants/Inclusion and exclusion criteria

Entry criteria: Erectile dysfunction, age 30 to 70 years
Exit criteria: Patients with anatomical problems in the penis, other sexual disorders, spinal cord injuries, heart attack in the past six months, stroke, treatment with mineral nitrates, gastric ulcer, migraine, visual impairment and allergic rhinitis

Intervention groups

In the sildenafil gel group, the topical sildenafil gel was given. A placebo tablet is also given to the patient to take an hour before sexual contact. In the oral pill group, an oral dose of sildenafil is consumed. Also, a placebo gel is placed on the male penis. In a placebo group, patients will receive a placebo tablet and placebo gel before sexual contact.

Main outcome variables

Erection, increasing the IIEF, improving the parameters of the penis color Doppler ultrasonography after sexual stimulation, increasing spouse's satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092429960N1**

Registration date: **2016-12-01, 1395/09/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-07, 1398/08/16**

Update count: **2**

Registration date

2016-12-01, 1395/09/11

Registrant information

Name

Farshad Sheibani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8889 3974

Email address

f-sheybaem@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Chemical injuries research center of Baqiatollah University

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2016-10-22, 1395/08/01

Actual recruitment end date

2018-12-22, 1397/10/01

Trial completion date

2018-12-22, 1397/10/01

Scientific title

Comparison of the therapeutic effect of topical sildenafil gel and oral sildenafil pill in patients with erectile dysfunction

Public title

Comparison of the therapeutic effect of topical sildenafil gel and oral sildenafil pill in patients with erectile dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 30 to 70 years having erectile dysfunction

Exclusion criteria:

Penile anatomic abnormalities other sexual dysfunctions
spinal cord injuries Acute myocardial infarction within
last 6 months Cerebrovascular accident nitrate drug use
Peptic ulcer disease Migrane visual disturbances Allergic
rhinitis

Age

From **30 years** old to **70 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients will be randomized with a blocked randomization technique. The treatment group will be assigned with Excel software and use of Rand Function. Patients will be grouped into four-person groups. Physician and patients are not informed about treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present study, the physician and the drug provider will not be aware of the type of treatment and the group of patients. All patients will receive tablets and gels that have the same appearance and are not aware of the treatment group. Medications with labels A and B are indicated for final analysis and return of results.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Pour Sina alley, Keshavarz Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2016-07-18, 1395/04/28

Ethics committee reference number

IR.TUMS.REC.1395.16

Health conditions studied

1

Description of health condition studied

Erectile dysfunction

ICD-10 code

F52.2,N48.

ICD-10 code description

The principal problem in men is erectile dysfunction (difficulty in developing or maintaining an erection suitable for satisfactory intercourse),

Primary outcomes

1

Description

Sexual satisfaction of patient

Timepoint

before intervention, one month after intervention

Method of measurement

International index of erectile function questionnaire (IIEF)

2

Description

Sexual satisfaction of patient's sexual partner

Timepoint

before intervention, one month after intervention

Method of measurement

sexual partner satisfaction questionnaire

3

Description

Dorsal penile artery PSV

Timepoint

before intervention, two weeks after intervention

Method of measurement

Color doppler sonography of the penis

4

Description

Dorsal penile vein EDV

Timepoint

before intervention, two weeks after intervention

Method of measurement

Color doppler sonography of the penis

5

Description

Dorsal penile artery RI

Timepoint

before intervention, two weeks after intervention

Method of measurement

Color doppler sonography of the penis

6

Description

Erection quality

Timepoint

before intervention, one month after intervention

Method of measurement

rigidity of the penis during sexual contact based on patient interview

7

Description

Erection time

Timepoint

before intervention, one month after intervention

Method of measurement

The stability of erection before orgasm or ejaculation based on patient interview

Secondary outcomes

1

Description

complication

Timepoint

during study and one month after intervention

Method of measurement

based on patient interview

Intervention groups

1

Description

Oral sildenafil pill 50 mg one hour before sexual contact for one month in intervention group

Category

Treatment - Drugs

2

Description

Topical sildenafil gel which applied half an hour before sexual contact on penis for one month in intervention group

Category

Treatment - Drugs

3

Description

Placebo Pill and Placebo Gel before sexual contact for one month in control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebn Abitaleb Hospital

Full name of responsible person

Farshad Sheibani

Street address

Ali Ebn Abitaleb Hospital, Khalij E Fars Blvd., Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Fax

+98 54 3329 5570

Email

f-sheybaem@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Yunes Panahi

Street address

Tehran University of Medical Sciences, Pour Sina alley, Keshavarz Blvd., Tehran

City

Tehran

Province

Tehran

Postal code
1417653761

Phone
+98 21 8889 3974

Fax
+98 21 8889 3974

Email
yunespanahi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tehran 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

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Farshad Sheibani

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Urology

Street address
Tehran University of Medical Sciences, Pour Sina alley, Keshavarz Blvd., Tehran

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1417653761

Phone
+98 21 8889 3974

Fax
+98 21 8889 3974

Email
f-sheybaem@razi.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person
Farshad sheibani

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Urology

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Tehran

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1417653761

Phone
+98 21 8889 3974

Fax
+98 21 8889 3974

Email
f-sheybaem@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Farshad Sheibani

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Urology

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+98 21 8889 3974

Fax
+98 21 8889 3974

Email
f-sheybaem@razi.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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
Yes - There is 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

Title and more details about the data/document

all collected deidentified IPD

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
only available for people working in academic institutions

Under which criteria data/document could be used
Data will be available for re-analysis and also for use in meta-analysis

From where data/document is obtainable
f-sheybaeem@razi.tums.ac.ir

What processes are involved for a request to access data/document
Inform the responsible person via email and after coordination with Dr. Younes Panahi, the data will be available.

Comments