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)
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+98 21 8889 3974
Email address
f-sheybaeem@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 committe 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
regidity 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
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9816743111
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f-sheybaeem@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
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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
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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