

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Study of the effect of continuous use of Tadalafil on men's sexual function after posterior urethroplasty surgery - clinical trial

Protocol summary

Study aim

survey of continuous use of tadalafil after posterior in men's sexual function

Design

Two arm parallel RCT with treatment and placebo arms ,double-blinded, on 80 patients

Settings and conduct

The study is performed in the clinic of Imam Reza hospital in Tabriz ,by International Index of Erectile Dysfunction (IIEF) questionnaires that will be completed at least 2 weeks after the surgery and 4 weeks and 3 months after first evaluation, By either patient or physician and after proper guiding of how to fill the questionnaire . Blinding is performed by the analyzer according to the mentioned drugs and matching forms. In this study, physician will provide the drugs for patients and give it to them based on matching forms and both physician and patient, will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men eligible for posterior urethroplasty
Exclusion criteria: Absence of Sexual dysfunction at presentation Physical inability for sexual intercourse

Intervention groups

The patients who are candidates for posterior urethroplasty will be divided into two homogenous groups. One group will undergo Tadalafil (10 mg per day) treatment starting at least two week after surgery and the other group will receive placebo.

Main outcome variables

The effect of continuous use of tadalafil versus placebo in patients undergoing posterior urethroplasty; The prevalence of erectile dysfunction in the patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201111049350N1**

Registration date: **2020-12-25, 1399/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-15, 1400/02/25**

Update count: **1**

Registration date

2020-12-25, 1399/10/05

Registrant information

Name

Hamedreza Nourian kafshgari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3387 8734

Email address

hamedrezanourian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of continuous use of Tadalafil on men's sexual function after posterior urethroplasty surgery - clinical trial

Public title

Effect of continuous use of Tadalafil on men's sexual

function after surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men eligible for posterior urethroplasty whom visited at Urology clinic, Imam Reza hospital, Tabriz

Exclusion criteria:

Absence of erectile dysfunction at presentation, or anytime during study Physical inability to perform sexual intercourse

Age

No age limit

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical sciences

Street address

Urology departement- Imam reza hospital - Golgasht st - Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2020-12-08, 1399/09/18

Ethics committee reference number

IR.TBZMED.REC.1399.829

Health conditions studied

1

Description of health condition studied

Erectile dysfunction

ICD-10 code

N52

ICD-10 code description

Male erectile dysfunction

Primary outcomes

1

Description

Suffering of Erectile dysfunction before and after posterior Urethroplasty

Timepoint

At least 2 weeks After surgery, 4 weeks and 3 months after first evaluation

Method of measurement

The international index of erectile function questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Continuous consumption of Tadalafil 10 mg tablet, daily after surgery and at least 3 months after surgery, During sessions, we'll inform patients about filling the questionnaire and discuss about possible side effects.

Category

Treatment - Drugs

2

Description

Control group: Continuous consumption of placebo tablet, daily after surgery and at least 3 months after surgery, During sessions, we'll inform patients about filling the questionnaire and discuss about possible side effects.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Farzin Soleimanzadeh Ardebili

Street address

Imam Reza hospital - Golgasht st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Hamedreza Nourian kafshgari
Position
Resident
Latest degree
Medical doctor

Other areas of specialty/work

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Yes - There is 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

Specific participant data sets are to be shared

When the data will become available and for how long

starting 6 months after publication)

To whom data/document is available

This is available for people working in academic institutions and people working in related businesses.

Under which criteria data/document could be used

For use in other studies (meta-analysis)

From where data/document is obtainable

Emailing via Corresponding author Hamedreza Nourian Kafshgari, Urology department, Imam Reza hospital, Tabriz University of Medical Sciences
Hamedrezanourian@gmail.com

What processes are involved for a request to access data/document

After confirmation of Corresponding author and Urology departament of Tabriz medical University, Information will be provided considering confidentiality

Comments