

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of effectiveness of Tadalafil versus placebo on lower urinary tract symptoms in male patients with ureteral stent, A randomized controlled trial

Protocol summary

Summary

1- Objectives: Ureteral stenting is a common intervention in endo-urological procedures. Despite the usefulness of stents, however, patients experience various stent-related symptoms. Lower urinary tract symptoms have significant impacts on patients' health related quality of life. There are several medical modalities for symptom relief, and Tadalafil is one of the recent therapeutic options. This study is designed to evaluate the effects of Tadalafil on alleviation of lower urinary tract symptoms, pain, general health, sexual life and also work status of patients with ureteral stents based on Ureteral Stents Symptom Questionnaire. 2- Design: In this Randomized Controlled Trail, patients were randomly allocated to the intervention (Tadalafil) or Placebo groups after a computer based random block designation and receive encoded drug packages by head nurse of surgery room, who is unaware of the research process. None of the physicians, nurses, patients, outcome assessor and statistical analyzers is aware of designated intervention. 3- Setting and Conduct: Patients receive treatment with Tadalafil or placebo for 4 weeks after ureteral stent insertion and first follow up session was programmed to be 4 weeks after intervention. 4- Participants: Inclusion criteria: Male patients (+15 years) who underwent unilateral ureteral stenting. Exclusion criteria : Hypertension; history of heart disease; respiratory disease; stroke; hypotension; renal or liver failure; retinitis pigmentosa; severe headache; consumption of nitrate drugs and a positive urine culture, or who had any allergic reaction to Tadalafil 5- Interventions: Patients receive interventions randomly (Tadalafil or placebo) for 4 weeks with a daily pill. 6- The main outcome variables: The rate of stent related lower urinary tract symptoms (lower urinary tract symptoms, pain, general health, sex and working status) and secondary outcomes are the possible side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013113015597N1**
Registration date: **2014-02-19, 1392/11/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-02-19, 1392/11/30

Registrant information

Name

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Name of organization / entity

Urology Department - Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-12-06, 1392/09/15

Expected recruitment end date

2014-03-06, 1392/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of Tadalafil versus placebo on lower urinary tract symptoms in male patients with ureteral stent, A randomized controlled trial

Public title

Efficacy of Tadalafil on Lower Urinary tract Symptoms of patients with ureteral stents

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male patients (+15 years) that underwent unilateral ureteral stenting. Exclusion criteria: Patient's refusal of study; high blood pressure; history of heart disease; history of respiratory disease; history of stroke; hypotension (systolic blood pressure less than 90 mmHg); hepatic and renal failure; history of retinitis pigmentosa; severe headache; consumption of nitrate drugs and a positive urine culture

Age

From **15 years** old to **70 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Tadalafil and placebo were packed by pharmacologist colleagues in similar packages of 35 identical numbers, and as A1, B2, B3, A4 ... were encoded. None of physicians, nurses, patients and statistical analyzers is aware of Coding method. The patients receive one of the packages randomly.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Vice Chancellor for Research, Tabriz University of Medical Sciences, Daneshgah st, Tabriz

City

Tabriz

Postal code

Approval date

2013-09-11, 1392/06/20

Ethics committee reference number

9291

Health conditions studied

1

Description of health condition studied

LUTS associated with ureteral stents

ICD-10 code

R30-39

ICD-10 code description

hematuria, dysuria, pain , urgency , frequency, incontinance

Primary outcomes

1

Description

Urinary symptoms (urgency; frequency; nocturia; dysuria; hematuria; incomplete emptying) in patients with ureteral stents

Timepoint

4 Weeks after intervention (only at the end of study)

Method of measurement

Standard questionnaire (USSQ)

2

Description

Abdominal pain, flank pain, inguinal and genital pain and pain severity and its association with physical activity, rest, voiding,... in patients with ureteral stent

Timepoint

4 Weeks after intervention (only at the end of study)

Method of measurement

Standard questionnaire (USSQ)

3

Description

General health in patient with ureteral stent

Timepoint

4 Weeks after intervention (only at the end of study)

Method of measurement

Standard questionnaire (USSQ)

4

Description

Sexual matters in patients with ureteral stent

Timepoint

4 Weeks after intervention (only at the end of study)

Method of measurement

Standard questionnaire (USSQ)

5

Description

Work performance in patients with ureteral stent

Timepoint

4 Weeks after intervention (only at the end of study)

Method of measurement

Standard questionnaire (USSQ)

Secondary outcomes

1

Description

Cardiovascular side effects

Timepoint

4 Weeks after intervention (only at the end of study)

Method of measurement

Questionnaire

2

Description

Musculoskeletal side effects

Timepoint

4 Weeks after intervention (only at the end of study)

Method of measurement

Questionnaire

Intervention groups

1

Description

In the intervention group, tadalafil tablet (Chemidarou company) 10 mg once daily is given for 4 weeks by oral route.

Category

Treatment - Drugs

2

Description

In the control group, a placebo tablet (same shape, size and color of tadalafil which was made from starch by Pharmacy faculty of Tabriz University of Medical Sciences) is given for 4 weeks by oral route.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital - Tabriz University of Medical Sciences

Full name of responsible person

Dr Sakineh Hajebrahimi - Professor of Urogynecology

Street address

Imam Reza Hospital, Golgasht st, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Hossein Babaei

Street address

Drug Applied Research Center, Daneshgah st, Tabriz

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Tabriz

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

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 Department, Tabriz University of Medical Sciences

Full name of responsible person

Dr Abbas Jabbari

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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