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
Abbas Jabbari
Name of organization / entity
Urology Department - Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1335 7328
Email address
abbasjabbari@yahoo.com

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
City
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
Position
Urology Assistant
Other areas of specialty/work
Street address
Imam Reza Hospital, Tabriz
City
Tabriz
Postal code
5155969748
Phone
+98 41 1335 7328
Fax
+98 41 1335 7328
Email

abbasjabbari@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Urology Department, Tabriz University of Medical Sciences

Full name of responsible person
Dr Sakineh Hajebrahimi

Position
Professor of Urogynecology

Other areas of specialty/work

Street address
Imam Reza Hospital, Tabriz

City
Tabriz

Postal code

Phone
+98 41 1334 7054

Fax
+98 41 1335 7328

Email
hajebrahimis@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Urology Department, Tabriz University of Medical Sciences

Full name of responsible person
Dr Abbas Jabbari

Position
Urology Assistant

Other areas of specialty/work

Street address
Imam Reza Hospital, Tabriz

City
Tabriz

Postal code
5155969748

Phone
+98 41 1335 7328

Fax
+98 41 1335 7328

Email
abbasjabbari@yahoo.com

Web page address

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