Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A comparative study on the therapeutic effect of tamsulosin, tadalafil and placebo in stone expulsion of patients with distal ureteral stones

Protocol summary

Summary

Urinary stones are one of the most common diseases of the urology. Its treatments are both surgical and medicinal. Tamsulosin is the most commonly used alpha-blocker, which has a proven role in increasing the rate of expulsion, as well as decreasing expulsion time. Recently, phosphodiesterase inhibitors such as tadalafil have been considered in the treatment of urinary stones. In this randomized, double blind clinical trial, 132 patients with lower ureteral stones, aged 18 to 65 years old, and having a single distal ureteral stone, smaller than 10 mm, will be included. Patients with GFR <30; single kidney; multiple ureteral stones; history of open or endoscopic surgery in the urinary tract and diabetes will be excluded. First, all patients will undergo physical examination, and laboratory and imaging (CT scans without contrast) will be requested. Patients will be randomly divided into three groups by random allocation, treated with: tamsulosin 0.4mg daily (group 1), tadalafil 10mg daily (group 2), and placebo (group 3). All patients with renal colic will receive diclofenac 100mg oral or suppository, and in the absence of improvement, 50mg intravenous pethidine will be prescribed. If there is a resistant colic, an emergency treatment intervention will be taken. A filter or cloth for urine filtering will be used by patients to diagnose stone expulsion. Patients will be monitored for every 2 weeks (up to a maximum of 4 weeks) until stone expulsion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709191853N14**
Registration date: **2017-11-20, 1396/08/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name

Siavash Falahatkar

Name of organization / entity

Urology Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 3352 5259

Email address

urc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Urology Research Center, Guilan University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the therapeutic effect of tamsulosin, tadalafil and placebo in stone expulsion of patients with distal ureteral stones

Public title

The therapeutic effect of tamsulosin and tadalafil in stone expulsion of patients with ureteral stones

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients 18-65 years of age; individual dilated ureteral stone with a size smaller than 10mm lower than Common Illiac vascular by contrast-free CT scan; patients whose colic with a single dose of diclofenac (100mg oral or suppository) and, if not recovered, with a single dose of pethidine (50mg intravenous) in one day is improved. Exclusion criteria: Fever; patients with GFR <30; single kidney; multiple ureteral stones; history of endoscopic surgery or open surgery in the urinary tract; diabetes; gastric ulcer; concomitant treatment with alpha-blockers, calcium or nitrate antagonists; pregnant or lactating mothers; any allergic reaction to drugs used; patients requiring surgical or endoscopic intervention following non-pain relief during drug intervention (resistant colic); uremic symptoms; urinary retention; patients who have an urge to receive immediate medical intervention.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Study is randomly double-blinded. Selection of each of the pharmaceutical packs (thamsulosin, tadalafil, placebo) for patients will be based on six random blocks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Rasht, Gas Sq., West Shahid Beheshti Blvd., opposite of Sepah Bank

City

Rasht

Postal code

41938-93345

Approval date

2017-04-29, 1396/02/09

Ethics committee reference number

IR.GUMS.REC.1396.41

Health conditions studied

1

Description of health condition studied

Ureter stone

ICD-10 code

N20.1

ICD-10 code description

Calculus of ureter

Primary outcomes

1

Description

Stone expulsion

Timepoint

2 and 4 weeks after intervention

Method of measurement

Stone expulsion by patient's observation, CT scan without contrast in case of not observing stone expulsion

Secondary outcomes

empty

Intervention groups

1

Description

Tamsulosin capsule with a dose of 0.4 mg made in Iran, one daily for a maximum of 4 weeks

Category

Treatment - Drugs

2

Description

Tadalafil tablets with a dose of 10 mg in capsule cover made in Iran, one daily for a maximum of 4 weeks

Category

Treatment - Drugs

3

Description

Placebo capsule made in Iran, one daily for a maximum of 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Dr. Ardalan Akhavan

Street address
Razi Hospital, Sardar Jangal Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Urology Research Centre, Guilan University of Medical Sciences

Full name of responsible person
Head of Urology Research Centre, Dr. Siavsh Falahatkar

Street address
Urology Research Centre, Razi Hospital, Sardar Jangal Street

City
Rasht

Grant name
10506

Grant code / Reference number
32

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Urology Research Centre, Guilan 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 Research Center, Guilan University of Medical Sciences

Full name of responsible person
Dr. Ardalan Akhavan

Position
Resident of Urology/ Co worker

Other areas of specialty/work

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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