

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of tamsulosin on lower ureteral stone expulsion

Protocol summary

Summary

The aim of this study is evaluation of efficacy of tamsulosin on lower ureteral stone expulsion . Study design: researcher After explaining the purpose of the study and obtaining the informed consent of patients randomly divided into two treatment groups A and B are.The groups will be treated, randomized, single-blind, placebo-free, single-center, phase 3 trial Study population: patients admitted to Imam Hussein hospital with a kidney stone Inclusion criteria for the project: Patients between the ages of 18 and 60 years in with renal colic with 3 to 6 mm stones in distal ureteral or ureteral uvj Exclusion criteria: UTI; Radiolucent stones on KUB; sever Hydronephrosis (grades 2 and 3 in ultrasound; Diabetes (FBS more than 125 milligrams per deciliter); history of peptic ulcer disease; Systolic blood pressure less than 100 mm Hg; Consumers calcium antagonist drugs; history of surgery on the distal ureter; single kidney ; creatinine more than 1.4 mg per deciliter in men and 1.2 in women; Intractable pain; NSAID intolerance ; side effects of tamsulosin; pregnancy Sample size: 100 patients participated in the 50 patients in any branch The intervention used in the study: Tamsulosin 4 mg orally Intervention time: Prescribed time period prescribed tamsulosin morning and until the stone or in case of expulsion for up to four weeks after the start of the study will be Primary outcomes: Stone expulsion time, Stone expulsion rate

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012626211N1**
Registration date: **2016-05-25, 1395/03/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-25, 1395/03/05

Registrant information

Name

Naghme Ahi

Name of organization / entity

Islamic Azad University of Shahrood

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Recruitment status

Recruitment complete

Funding source

adjutancy of Research and Technology, Islamic Azad University of Shahrood

Expected recruitment start date

2016-04-13, 1395/01/25

Expected recruitment end date

2018-04-14, 1397/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of tamsulosin on lower ureteral stone expulsion

Public title

The effect of tamsulosin on ureteral stones expulsion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria for the project: Patients between the ages of 18 and 60 years in with renal colic with 3 to 6 mm stones in distal ureteral or ureteral uvj Exclusion criteria: UTI; Radiolucent stones on KUB; sever

Hydronephrosis (grades 2 and 3 in ultrasound; Diabetes (FBS more than 125 milligrams per deciliter); history of peptic ulcer disease; Systolic blood pressure less than 100 mm Hg; Consumers calcium antagonist drugs; history of surgery on the distal ureter; single kidney ; creatinine more than 1.4 mg per deciliter in men and 1.2 in women; Intractable pain; NSAID intolerance ; side effects of tamsulosin; pregnancy

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahroud University of Medical Sciences

Street address

Hafte-Tir Square, Shahroud University of Medical Sciences

City

Shahroud

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

930/08

Health conditions studied

1

Description of health condition studied

kidney stone

ICD-10 code

N20.1

ICD-10 code description

Calculus of ureter

Primary outcomes

1

Description

Stone expulsion rate

Timepoint

4 weeks after treatment

Method of measurement

Questionnaire

2

Description

Stone expulsion time

Timepoint

4 weeks after treatment

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Amount of sedative

Timepoint

4 weeks after treatment

Method of measurement

Questionnaire

2

Description

Drug side effects

Timepoint

4 weeks after treatment

Method of measurement

Questionnaire

3

Description

Stone complications

Timepoint

4 weeks after treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention: Oral tamsulosin 4 mg Intervention method: Prescribed tamsulosin Morning, and for prescribing it until the stone is Or in case of expulsion for up to four weeks after initiation of the study. All patients from both groups to allow the use of 100 mg indomethacin treatment for symptomatic PRN (in case of unbearable

pain) is given. All patients from both groups emphasized that drink 2 liters of water daily.

Category

Treatment - Drugs

2**Description**

Control:Non-use of tamsulosin oral 4mg Control Method: All patients from both groups to allow the use of 100 mg indomethacin treatment for symptomatic PRN (in case of unbearable pain) is given. All patients from both groups emphasized that drink 2 liters of water daily.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hussein Hospital

Full name of responsible person**Street address****City**

Shahroud

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

adjutancy of Research and Technology, Islamic Azad University of Shahrood

Full name of responsible person

Dr sahebali manafi

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Islamic Azad University of Shahroud, Tehran Blvd

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shahroud

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

adjutancy of Research and Technology, Islamic Azad University of Shahrood

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**

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Full name of responsible person

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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