Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 Shahroud
Country
Iran (Islamic Republic of)
Phone
+98 936 123 2544
Email address
n-ahi@iau-shahrood.ac.ir

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

Street address

Islamic Azad University of Shahroud, Tehran Blvd

City

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

Islamic Azad University of Shahroud

Full name of responsible person

Naghme Ahi

Position

Medical Student

Other areas of specialty/work

Street address

Islamic Azad University of Shahroud, Tehran Blvd

City

Shahroud

Postal code

Phone

+98 23 3239 0077

Fax

Email

N-Ahi@iau-shahrood.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Imam Hussein Hospital- University of Medical Sciences shahroud

Full name of responsible person

Vahid Bolurian

Position

Urologist

Other areas of specialty/work

Street address

Islamic Azad University of Shahroud, Tehran Blvd

City

Shahroud

Postal code

Phone

+98 23 3239 0077

Fax

Email

Sadrv@ymail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University of Shahroud

Full name of responsible person

Mania Armin

Position

Medical Student

Other areas of specialty/work

Street address

Islamic Azad University of Shahroud, Tehran Blvd

City

Shahroud

Postal code

Phone

+98 23 3239 0077

Fax

Email

mania_armin@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