

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The efficacy of tamsulosin in facilitating expulsion of distal urethral calculi.

Protocol summary

Summary

The aim of the study is to consider the efficacy of the Tamsulosin in facilitating the expulsion of stones and reducing the time of the expulsion of stones and needed to the analgesics in the patients suffered distal urethral calculi. Design: not blinded clinical trial. Exclusion criteria include: Multiple urethral stones; renal insufficiency; urinary tract infection; a solitary kidney; or pregnancy; history of urethral surgery; hypersensitivity to Tamsulosin; current alpha-blocker; calcium-antagonist medication; acute hydronephrosis; diabetic patients; hypertension; Obesity illnesses; use of another drugs at the same period (analgesic or anti-inflammatory ones), and complications of Tamsulosin (dizziness - tachycardia...). Entrance criteria includes: all patients with stone size of 3-10mm. Patients with the distal urethral stones distinguished by sonography or KUB or spiral computed tomography are divided into two groups: A and B. The capsule of Tamsulosin 0.4mg and the suppository of Diclofenac Sodium 50mg Q8h and a single dose of Dexamethazone 8mg (inj) are given to the patients in A group. A similar therapeutic diet is given to the patients of group B, except of Tamsulosin. Each 3 days, the questionnaire of No 2 is completes for the patients. Every patient is controlled with KUB or sonography each one or two weeks. The patients are followed up until they expel the stones, or for 4 weeks. Main outcome measures: facilitating of expulsion of stone

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111168114N1**

Registration date: **2012-04-10, 1391/01/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-10, 1391/01/22

Registrant information

Name

Mostafa, Neda Avarjeh, Nabizade Moghadam

Name of organization / entity

Birjand University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 56144430416

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Birjand University of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of tamsulosin in facilitating expulsion of distal urethral calculi.

Public title

The efficacy of tamsulosin in facilitating expulsion of stones in the patients with distal urethral calculi.

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria include: Multiple urethral stones; renal insufficiency; urinary tract infection; a solitary kidney; or pregnancy; history of urethral surgery; hypersensitivity to Tamsulosin; current alpha-blocker; calcium-antagonist medication; acute hydronephrosis; diabetic patients; hypertension; Obesity illnesses; use of another drugs at the same period (analgesic or anti-inflammatory ones), and complications of Tamsulosin (dizziness - tachycardia...). Entrance criteria includes: all patients with stone size of 3-10mm.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand university of medical science

Street address

Birjand University of Medical Sciences, Ghafari Blvd, Birjand

City

Birjand

Postal code

Approval date

2011-12-10, 1390/09/19

Ethics committee reference number

579

Health conditions studied

1

Description of health condition studied

Distal ureteral calculi

ICD-10 code

N20.1

ICD-10 code description

Calculus of ureter

Primary outcomes

1

Description

of repelling stone

Timepoint

Once every three days, for 4 weeks

Method of measurement

The statements sick

Secondary outcomes

1

Description

The rate of consumption suppository diclofenac

Timepoint

once every three days, for 4 weeks

Method of measurement

The statements sick

2

Description

The days of repelling stone

Timepoint

once every three days, for 4 weeks

Method of measurement

According to answer the phone patients based on the removal of stone

Intervention groups

1

Description

Case Group : The capsule of Tamsulosin 0.4 mg and the suppository of Diclofenac Sodium 50 mg Q8h and a single dose of Dexamethazone 8mg (inj) are given to. Treatment will continue for 4 weeks, or till expulsion.

Category

Treatment - Drugs

2

Description

Control Group : The suppository of Diclofenac Sodium 50mg Qh and a single dose of Dexamethazone 8mg (inj) are given to. Treatment will continue for 4 weeks, or till expulsion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dear doctor's office Mr. Mohammad Njafi

Full name of responsible person

Mr. Dr. Mohammad Njafi

Street address

Taleghani street, Birjand, Southern Khorasan

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Birjand University of Medical Sciences

Full name of responsible person

Mr. Dr. Mohammad Njafi

Street address

Birjand University of Medical Sciences, Ghafari Blvd, Birjand

City

Birjand

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Birjand 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

Birjand University Of Medical Science

Full name of responsible person

Mr.Dr. Mohammad Njafi

Position

Urologist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Mostafa Avarjeh

Position

Medical student

Other areas of specialty/work

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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