

# 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)

###### Phone

+98 56144430416

###### Email address

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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**

**Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Mostafa Avarjeh

**Position**

Medical student

**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*