

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### study of efficacy & side effects of oral cystone & hydrochlorothiazide in treatment of patients older than 15 years old suffering from kidney & ureteral calculi

#### Protocol summary

##### Study aim

comparison efficacy of oral cystone and Hydrochlorothiazide in treatment of kidney and ureteral stones (5\_10mm) in Shahid Mofateh clinic of Yasuj in 2018\_ 2019

##### Design

In this randomized ,parallel group clinical trial from January 2018 to January 2019 with simple sampling methods eighty (80) patients older than 15 years old allocated in one of two groups and received intervention for one months .

##### Settings and conduct

Patients referring to Shahid Mofateh clinic of Yasuj suffering from renal or ureteral stones 5-10 millimeter with simple sampling method allocated in one of two groups. All patients have history and physical exam and basic serum samples including renal function tests(BUN ,Cr),urine analysis and culture will be checked from all of them. In two groups use oral analgesic for pain relief and in the failure of analgesic or indication of intervention standard treatment will be done. It is also recommended that at least 30 minutes of exercise and walking will be done per day .One and three months later, the patients were re-examined and KUB or ultrasonography was performed and the success of the treatment was measured and recorded according to the size of the stone and the presence of remaining gems.

##### Participants/Inclusion and exclusion criteria

Patients older than 15 years old with kidney and ureteral stones sized 5- 10 mm after taking informed consent form and approval of the ethics committee included in the study . Patients with severe cardiovascular and pulmonary disease, azotemia, urinary tract infection, coagulopathy, pregnant ladies and those that have i history of herbal or medicinal allergy don't enter the study.

##### Intervention groups

intervention group: 2 tablet of oral cystone every 12 hours with a glass of water for one month Control group: Hydrochlorothiazide Tablets 25 milligram every 12 hour with a glass of water for one month

##### Main outcome variables

change in the size and passage of stones

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20081011001323N15**

Registration date: **2018-03-14, 1396/12/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-14, 1396/12/23**

Update count: **0**

##### Registration date

2018-03-14, 1396/12/23

##### Registrant information

##### Name

Sadrollah Mehrabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3334 6070

##### Email address

dr.mehrabi@yums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-01-21, 1396/11/01

##### Expected recruitment end date

2019-01-21, 1397/11/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
study of efficacy & side effects of oral cystone & hydrochlorothiazide in treatment of patients older than 15 years old suffering from kidney & ureteral calculi

**Public title**  
comparison of cystone & hydrochlorothiazide in treatment of kidney stone

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

age more than 15 years old suffering from renal or upper ureteral stone less than 10 millimeter Having informed consent form

**Exclusion criteria:**

Uncontrolled coagulopathy Azotemia Pregnancy Presence of active urinary tract infection Allergy to medical or herbal drugs Severe cardiovascular or pulmonary disease

**Age**

From 15 years old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 80

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are allocated with simple sampling methods to one of each group and received the intervention of that group.

**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 Yasuj University of Medical Sciences

**Street address**

Yasuj University of Medical Sciences, Mottahari srteet, Yasuj, Iran

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

7591741417

**Approval date**

2018-01-10, 1396/10/20

**Ethics committee reference number**

IR.YUMS.REC.1396.156

**Health conditions studied**

1

**Description of health condition studied**

Calculus of kidney and ureter

**ICD-10 code**

N20.2

**ICD-10 code description**

Calculus of kidney with calculus of ureter

**Primary outcomes**

1

**Description**

Passage of renal and upper ureteral stones sized 5-10 millimeter

**Timepoint**

Two weeks and one month after start of treatment

**Method of measurement**

Taking KUB and Ultrasonography and report of patients

**Secondary outcomes**

1

**Description**

development of side effects

**Timepoint**

from start of treatment to one month later

**Method of measurement**

according to history and physical exam and patient report

**Intervention groups**

1

**Description**

Intervention group: Cystone Tablets take 2 tablets with one glass of water every 12 hours for one month

**Category**

Treatment - Drugs

## 2

### Description

Control group: Hydrochlorothiazide Tablets 25 miligram every 12 hour with a glass of water for one month

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shahid Mofateh clinic

**Full name of responsible person**

Sadrolleh Mehrabi

**Street address**

No.22 , Shahid Madani street, Bahonar Blvd, Yasuj, Iran

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591741414

**Phone**

+98 74 3322 8213

**Email**

dr.mehrabi@yums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Yasuj University of Medical Sciences

**Full name of responsible person**

Dr Ali Mousavizadeh

**Street address**

Vice chancellor for Research, Yasuj University of Medical Sciences, Mottahari Street, Yasuj, Iran

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591741417

**Phone**

+98 74 3334 6074

**Email**

health.epid@gmail.com

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

Yes

**Title of funding source**

Yasuj University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Yasuj University of Medical Sciences

**Full name of responsible person**

Sadrollah Mehrabi

**Position**

Professor Education vice chancellor, Yasuj University of Medical Sciences

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Urology

**Street address**

Vice chancellor for Education, Yasuj University of Medical Sciences, Mottahari Street, Yasuj, Iran

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591741417

**Phone**

+98 74 3334 6070

**Email**

dr.mehrabi@yums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Yasuj University of Medical Sciences

**Full name of responsible person**

Sadrollah Mehrabi

**Position**

professor, Fellowship of endourology and laparoscopy

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Urology

**Street address**

Vice chancellor for Education, Yasuj University of Medical Sciences, Mottahari Street, Yasuj, Iran

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7591741417

**Phone**

+98 74 3334 6070

**Email**

dr.mehrabi@yums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Sadrollah Mehrabi

**Position**

professor, Fellowship of endourology and laparoscopy

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Urology

**Street address**

Vice chancellor for Education, Yasuj University of  
Medical Sciences, Mottahari Street, Yasuj, Iran

**City**

Yasuj

**Province**

Kohgiluyeh-va-Boyer-Ahmad

**Postal code**

7591741417

**Phone**

+98 74 3334 6070

**Email**

dr.mehrabi@yums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available