

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

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Sadrollah Mehrabi

Position

professor, Fellowship of endourology and laparoscopy

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for updating data

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Position

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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