Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 than15 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-Boyrahmad

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 milimeter

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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dr.mehrabi@yums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj 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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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
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Sadrollah Mehrabi
Position
Professor Education vice chansellor, Yasuj University of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
Urology
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professor, Fellowship of endourology and laparoscopy
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

professor, Fellowship of endourology and laparoscopy

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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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