Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

To study the efficacy of Urtica herbal oral liquid on expulsion of urinary system stones

Protocol summary

Study aim
The effect of the herbal medicine Urtica on facilitating and time of kidney stones expulsion after extracorporeal lithotripsy

Design
Clinical trial with control group, parallel groups, randomized and double blinded

Settings and conduct
Adult patients presenting with kidney stones who have undergone extracorporeal lithotripsy in the lithotripsy department of Labafinejad Hospital will be randomly assigned to two groups treated with tamsulosin and urtica or tamsulosin and placebo. After collection of inform consent, all study variables (abdominal ultrasound or CT, urine analysis and culture, serum creatinine, liver function tests)will be collected. Then the patients will be randomized in two groups; Tamsulosine with Urtica OR Tamsulosine with placebo. After 6 weeks of intervention; abdominal ultrasound, serum creatinine, liver function tests and questionnair regarding stone expulsion status and drug intolerance will be assessed. During the study, all participants had the recommendations of water intake and pian killer drug (if recommended).

Participants/Inclusion and exclusion criteria
Adult patients undergoing extracorporeal lithotripsy without a history of chronic renal failure or heart disease

Intervention groups
Two groups of adult patients with kidney stone undergoing extra corporeal lithotripsy which randomly assigned under treatment with Tamsulosin with Urtica or Tamsulosine with placebo

Main outcome variables
Effect of Urtica on stone expulsion status in terms of size, frequency, stone expulsion time and severity of pain during expulsion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191026045244N5**
Registration date: **2026-08-13, 1405/05/22**
Registration timing: **retrospective**

Last update: **2026-08-13, 1405/05/22**
Update count: **0**

Registration date
2026-08-13, 1405/05/22

Registrant information

Name
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Name of organization / entity
Urology and Nephrology Research Center,Shahid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2021-09-23, 1400/07/01

Actual recruitment start date
2025-01-20, 1403/11/01

Actual recruitment end date
2025-08-22, 1404/05/31

Trial completion date
2025-11-21, 1404/08/30

Scientific title
To study the efficacy of Urtica herbal oral liquid on

expulsion of urinary system stones

Public title
Effect of herbal drug on expulsion of kidney stone
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referring to emergency department due to renal colic With evidence of kidney or ureteral stone 5 to 10 mm in abdominal ultrasound or CT scan Without evidence of urinary tract infection With normal kidney function
Exclusion criteria:
Persistant renal colic pain Need to any urgent surgical intervention such as ureteroscopy or stent in term of pregnant or lactating women Any symptoms related to drug hypersensitivity Diabetic patients History of urinary system surgery during last years ago
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **190**
More than 1 sample in each individual
Number of samples in each individual: **95**
95 patients in each groups of intervention and control
Actual sample size reached: **192**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients will be randomly assigned to the intervention group (receiving Urtica extract) or the control group (receiving a placebo) using the Block randomization method with blocks of four. An independent researcher, who has no role in patient recruitment or data analysis, will generate random sequences using the Random Allocation software.
Blinding (investigator's opinion)
Double blinded
Blinding description
To maintain blinding, the study medications were packaged in identical boxes with sequential numbers. The placebo appeared and was labeled identically to the active extract. Participants, investigators handling enrollment and treatment, and the data analyst will all be kept unaware of group assignments, ensuring triple blinding during the entire study
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Urology Nephrology Research Center
Street address
Pasdaran
City
Tehran
Province
Tehran
Postal code
1666663111
Approval date
2019-09-15, 1398/06/24
Ethics committee reference number
IR.SBMU.UNRC.REC.1398.019

Health conditions studied

1

Description of health condition studied
Calculus of kidney with calculus of ureter
ICD-10 code
Z00.6
ICD-10 code description
Examination for normal comparison and control in clinical research programme

Primary outcomes

1

Description
Effect of Urtica herbal drug on the size of expelled stone
Timepoint
6 weeks
Method of measurement
abdominopelvic ultrasound or CT

2

Description
Effect of Urtica herbal drug on the time of stone expulsion
Timepoint
6 weeks
Method of measurement
questionnaire

3

Description
Effect of Urtica herbal drug on pain severity during stone expulsion

Timepoint
6 weeks
Method of measurement
visual analogue scale

Secondary outcomes

1

Description
Effect of Urtica herbal drug on serum creatinine
Timepoint
6 weeks
Method of measurement
serum creatinine measurement

2

Description
Effect of Urtica herbal drug on liner function test
Timepoint
6 weeks
Method of measurement
Measuement of liver tests (ALT, AST)

Intervention groups

1

Description
Intervention group: Patient after extracorporeal lithotripsy of kidney or ureteral stones who is being treated with tamsulosin and urtica
Category
Treatment - Drugs

2

Description
Control group: Patient after extracorporeal lithotripsy of kidney or ureteral stones who is being treated with tamsulosin and placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
ESWL department of Labbafinejad hospital
Full name of responsible person
Dr Maryam Taheri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Abbas Baisi
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
95
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The information about the type of treatment and the results of intervetion on results of imaging and leb tests will be available.
When the data will become available and for how long
The data could be available one year after the published results.
To whom data/document is available
The data will be available for academic faculty members and researchers.
Under which criteria data/document could be used
The control of the data and supplementary analyses of the data could be performed under copyright law.
From where data/document is obtainable
Urology Nephrology Research Center
What processes are involved for a request to access data/document
Request email to first or corresponding author or research manager of UNRC
Comments
Data will be available if it used in review articles or in order to citation.