Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the Effect of Visipaque Contrast Material Use in Intravenous Urography on Expulsion or Displacement of Ureteral Stones

Protocol summary

Study aim
Evaluation of the Effect of Visipaque Contrast Material on the Expulsion or Displacement of Ureteral Stone

Design
Clinical trial with intervention and control groups, with parallel groups, without blinding, randomized using a random number table, on 92 patients

Settings and conduct
This clinical trial will be performed on 92 patients with ureteral stones in Shahid Beheshti Hospital of Hamadan University of Medical Sciences. Patients are divided into two groups of case and controls. In the case group, after performing the primary KUB and ultra-sonography, Intravenous urography (IVU) will be conducted with the help of Visipaque contrast material. After seeing IVU and confirming the diagnosis, 48 Hours later, secondary KUB will be taken and the stone expulsion and displacement will be compared between primary and secondary KUB. In the control group, 48 hours after confirmation of the stone in the primary ultra-sonography and KUB, the secondary KUB will be taken and the stone expulsion and displacement will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Iranian, Age of 10 to 70 years old, Ureter stone size <1 cm, without renal failure, Not being pregnant, Lack of sensitivity to contrast material, Do not take medications that affect on expulsion ureteral stone, Opaque stone. Exclusion Criteria: Unwillingness of patient, renal failure, Diabetic patients

Intervention groups
Intervention group: After confirmation of the stone in ultrasound and primary KUB, the patient will undergo Intravenous urography with a visipaque contrast material. Control group: After confirmation of the stone in the ultrasound and primary KUB, 48 hours later the secondary KUB will be taken.

Main outcome variables
Stone expulsion, stone displacement

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200616047796N1**
Registration date: **2021-01-03, 1399/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-03, 1399/10/14**
Update count: **0**

Registration date
2021-01-03, 1399/10/14

Registrant information

Name
Behzad Mohamadsoori

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3821 7363

Email address
drbehzadsoori@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-06-22, 1400/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the Effect of Visipaque Contrast Material Use in Intravenous Urography on Expulsion or Displacement of Ureteral Stones

Public title
The Effect of Visipaque Contrast Material on Expulsion or Displacement of Ureteral Stones
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian Age of 10 to 70 years old Ureter stone size less than 1 cm Opaque stone
Exclusion criteria:
Having renal failure Being pregnant Sensitivity to contrast material Take medications that affect on expulsion ureteral stone
Age
From **10 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
The present study is a randomized clinical trial. A simple randomization method and a random number table is used. In this way, a number will be selected randomly, if the number is even, the patient will enter the intervention group and if the number is odd, the patient will enter the second 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
کمیته اخلاق دانشگاه علوم پزشکی همدان
Street address
Eram Boulevard - Shahid Beheshti Hospital
City
Hamadan
Province
Hamadan
Postal code
3371-5-65179
Approval date
2019-12-08, 1398/09/17
Ethics committee reference number
IR.UMSHA.REC.1398.728

Health conditions studied

1

Description of health condition studied
Ureter Stone
ICD-10 code
N20.1
ICD-10 code description
Calculus of ureter

Primary outcomes

1

Description
Expulsion of ureter stone
Timepoint
48 hours later
Method of measurement
KUB imaging

2

Description
Displacement of ureter stone
Timepoint
48 hours later
Method of measurement
KUB imaging

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Conducting venous urography using Visipaque contrast material
Category
Treatment - Drugs

2

Description
Control group: Not doing venous urography
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital

Full name of responsible person
Dr. Sasan Mehrabi

Street address
Eram street

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3371565179

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+98 81 3838 1932

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dr.s.mehrabi@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Saeid Bashirian

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Fahmideh Street

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6517659114

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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
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Behzad Mohammad soori

Position
Resident of Urology

Latest degree
Medical doctor

Other areas of specialty/work
Urology

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Subspecialist

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Person responsible for updating data

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Medical doctor
Other areas of specialty/work
Urology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
We can share information about the main outcome. The data will spread unknown.
When the data will become available and for how long
The data will be an accessible 6-12 month after publishing the results.
To whom data/document is available
Researchers in academic institutes were allowed to access data
Under which criteria data/document could be used
With stating the reference
From where data/document is obtainable
Sending email to corresponding author through: dr.s.mehrabi@umsha.ac.ir
What processes are involved for a request to access data/document
An application letter must include the name of the applicant, used item, the scientific title of the research project or article and documents will be sent within two weeks of receiving the request.
Comments