

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 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

**City**

Hamadan

**Province**

Hamadan

**Postal code**

3371565179

**Phone**

+98 81 3838 1932

**Email**

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

**Street address**

Fahmideh Street

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517659114

**Phone**

+98 81 3838 0717

**Email**

s-bashirian@umsha.ac.ir

**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

**Street address**

Eram Street

**City**

Hamadan

**Province**

Hamadan

**Postal code**

3371-5-65179

**Phone**

+98 81 3838 1932

**Email**

drbehzadsoori@gmail.com

### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Sasan Mehrabi

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Urology

**Street address**

Eram street

**City**

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**Province**

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**Phone**

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**Email**

dr.s.mehrabi@umsha.ac.ir

### Person responsible for updating data

#### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Behzad mohamadsoori

**Position**

Resident of urology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

**Street address**

Eram street

**City**

Hamadan

**Province**

Hamadan

**Postal code**

3371-5-65179

**Phone**

+98 81 3838 1932

**Email**

drbehzadsoori@gmail.com

**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**