

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The effect of tamsulosin, hydrochlorothiazide or concomitant use of both in increasing the risk of stone excretion after ESWL Stones smaller than 2 cm Upper ureter

#### Protocol summary

##### Study aim

Determining the effect of tamsulosin, hydrochlorothiazide or concomitant use of both in increasing the risk of stone excretion after ESWL

##### Design

Patients will be grouped according to the Balanced Block Randomization method into four groups, A and B, C and D. All four drugs are in boxes A, B, C and D, and only the doctor in charge of the project is aware of the drug's content in each group. Then, for each patient, numbering is done by the supervisor and what is remembered in the office. For example, patient number 1 is drug A and patient number 2 is drug B, or vice versa, which is described below.

##### Settings and conduct

Kidneys are patients who have kidney stones in the upper ureter that are less than 2 cm in diameter on ultrasound and initial CT scan and are hospitalized at Shahid Hasheminejad Hospital in Tehran.

##### Participants/Inclusion and exclusion criteria

The subjects included all patients with kidney stones in the upper ureter who were less than 2 cm in diameter on ultrasound and initial CT scan and were admitted to Shahid Hasheminejad Hospital in Tehran, and were selected as a non-probable sequence. The criteria for withdrawal from the study include patient dissatisfaction at any stage of the study, lack of cooperation and non-use of the desired drugs, history of nephrolithiasis surgery, moderate and severe hydronephrosis, and renal failure.

##### Intervention groups

All patients are advised to limit their salt diet and increase their fluid intake. They are then randomly assigned to each of the groups studied. The first group with tamsulosin (0.4 mg ) and the second group with hydrochlorothiazide (25 mg twice daily), the third group under tamsulosin (0.4) mg / day) and

hydrochlorothiazide (25 mg twice daily) and the fourth group as the control group will receive only painkillers with placebo.

##### Main outcome variables

The effect of the drug on stone excretion

#### General information

##### Reason for update

##### Acronym

THSS

##### IRCT registration information

IRCT registration number: **IRCT20200704047998N1**

Registration date: **2020-11-17, 1399/08/27**

Registration timing: **retrospective**

Last update: **2020-11-17, 1399/08/27**

Update count: **0**

##### Registration date

2020-11-17, 1399/08/27

##### Registrant information

##### Name

Behnam Salehi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-22, 1398/03/01

##### Expected recruitment end date

2020-05-21, 1399/03/01  
**Actual recruitment start date**  
2019-05-22, 1398/03/01  
**Actual recruitment end date**  
2020-05-21, 1399/03/01  
**Trial completion date**  
2020-06-21, 1399/04/01

**Scientific title**

The effect of tamsulosin, hydrochlorothiazide or concomitant use of both in increasing the risk of stone excretion after ESWL Stones smaller than 2 cm Upper ureter

**Public title**

The effect of tamsulosin and hydrochlorothiazide on stone excretion

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All patients with ureteral stones below 2 cm are placed under a crusher

**Exclusion criteria:**

Stone above 2 cm upper ureter Severe and moderate hydronephrosis

**Age**

From **1 year** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **240**

Actual sample size reached: **200**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients were grouped according to Balanced Block Randomization method in four groups A and B, C and D. All four drugs were in boxes A, B, C and D, and only the doctor in charge of the project (supervisor) was aware of the drug content of each group. Then, for use for each patient, numbering was done by the supervisor and what was written in the office. For example, patient number 1 of drug A and patient number 2 of drug B or vice versa, how to blind it is described below. The main idea of block randomization was to divide patients into M blocks of size 2N, so that in each block N patients were assigned A and N patients were assigned to B. The block was then randomly selected. This method ensures equal treatment allocation per block provided the block is fully utilized. For example: two treatments A, B and block size  $2 \times 2 = 4$  Assignment of treatment is possible within each block (1) AABB (2) BBAA, (3) ABAB, (4) BABA, (5) ABBA, (6) BAAB The size of the block, depending on the number of

treatments, should be short enough to prevent imbalance, and large enough to prevent guessing treatment allocation in each group during the study. The block size should be at least twice the number of treatment nodes. The size of the block was stated in the study so that researchers would be blind to it. If the blocks were expressed, the treatment series in each block could be guessed. For example, in block 2N = 4, A A B must be B and in A A as B B can be deduced. This could lead to (selection bias). The solution to prevent this error was to: (1) not reveal the block mechanism. (2). Use random block size.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Patients are treated with pre-determined medication packages by the study supervisor (supervisor). The drug packages are quite similar in shape and the patient and the project manager are not aware of the contents of the packages. Forms are completed by the project manager and his assistant who are unaware of the contents of the packages; In the data analysis stage, the analysis will be performed by the project consultant and the project manager, who are not aware of the contents of the drug packages, and only the group of patients (group 1 or 2 or 3 or 4) will be identified for data analysis; Therefore, the study is three Socors and from the stage of the patient's entry into the study to the study, data collection and information analysis, the contents of the drug group are not clear

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Iran University of Sciences

**Street address**

Tehran. Valiasr St., Valinejad Alley. Shahid Hasheminejad Hospital

**City**

tehran

**Province**

Tehran

**Postal code**

1969714713

**Approval date**

2020-05-05, 1399/02/16

**Ethics committee reference number**

IR.IUMS.FMD.REC.1399.104

## Health conditions studied

### 1

#### Description of health condition studied

Renal stone

#### ICD-10 code

N20.1

#### ICD-10 code description

Calculus of ureter

## Primary outcomes

### 1

#### Description

stone passage

#### Timepoint

Immediately .A week. One Month . three months

#### Method of measurement

Patient history for stone removal

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first group was treated with tamsulosin (0.4 mg / day, manufactured by Daru Pakhsh Company, Tehran, Iran). Patients were followed up for 3 months and asked about stone removal, number of renal colic episodes, pain intensity based on VAS and the amount of analgesia used during 3 months after ESWL. Patients also underwent ultrasound and if the stone remaining in the follow-up was less than 4 mm, the removal of the stone was considered successful.

#### Category

Treatment - Drugs

### 2

#### Description

The second group was treated with hydrochlorothiazide (25 mg twice daily, made by Caspian Drug Company, Rasht, Iran). Patients were followed up for 3 months and asked about stone removal, number of renal colic episodes, pain intensity based on VAS and the amount of analgesia used during 3 months after ESWL. Patients also underwent ultrasound and if the stone remaining in the follow-up was less than 4 mm, the removal of the stone was considered successful.

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: , the third group was treated with

tamsulosin (0.4 mg / day) and hydrochlorothiazide (25 mg twice daily) and patients were followed for 3 months. Regarding stone removal, the number of renal colic episodes, Pain intensity was assessed based on VAS and the amount of analgesia used during 3 months after ESWL by asking patients. Patients also underwent ultrasound and if the stone remaining in the follow-up was less than 4 mm, the removal of the stone was considered successful.

#### Category

Treatment - Drugs

### 4

#### Description

Control group: The fourth group received only housing as a control group along with placebo. It should be noted that all study groups received analgesia in case of pain.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Hasheminejad hospital

##### Full name of responsible person

Moslem Poorakrami

##### Street address

Vali Asr Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1699714713

##### Phone

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##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Ali Taher

##### Street address

Shahid Hemmat Highway. Iran University of Medical Sciences

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##### Province

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**Email**

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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**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Behnam Salehi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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