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)

Phone

+98 21 8824 9214

Email address

salehi.b@iums.ac.ir

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 × 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
+98 21 81161
Email
Dr.behnam.salehi68@gmail.com

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
City
Tehran
Province
Tehran
Postal code
1699714713
Phone

+98 21 81161

Email

Dr.behnam.salehi68@gmail.com

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

Urology

Street address

Vali Asr Ave

City

Tehran

Province

Tehran

Postal code

1699714713

Phone

+98 21 81161

Email

Dr.behnam.salehi68@gmail.com

Person responsible for scientific 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

Urology

Street address

Vali Asr Ave

City

Tehran

Province

Tehran

Postal code

1699714713

Phone

+98 21 81161

Email

dr.behnam.salehi68@gmail.com

Person responsible for updating data

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

Urology

Street address

Vali Asr Ave

City

Tehran

Province

Tehran

Postal code

1699714713

Phone

+98 21 81161

Email

dr.behnam.salehi68@gmail.com

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