

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison between efficacy of Tamsulosin and Terazosinin alpha-adrenergic blockers in spontaneous passage of ureter stones after Extracorporeal Shock Wave Lithotripsy

Protocol summary

Study aim

Comparison of Tamsulosin and Terazosinin alpha blockers efficacy in ureter stones passage

Design

Randomised controlled trial with a control group and 2 parallel groups, single blinded with allocated envelopes on 240 patients with distal ureter stones

Settings and conduct

Admitted patients to Sabalan hospital of Ardabil with a radiopaque distal ureter stone whom are a candidate for extracorporeal shock wave lithotripsy are enrolled in to one of the 3 groups of this study randomly . Colicky pain episodes, lower urinary tract symptoms, pain reliever usage, days to repel stone and complications of medical treatment will be evaluated. Also patients will be also be evaluated by ultrasound in 2 week's time.

Participants/Inclusion and exclusion criteria

1. Patients with lower ureter stone with minimal size of 5 millimetr
2. Stone is radiopaque and is detectable on CT scan
3. Patient is a candidate of Extracorporeal Shock Wave Lithotripsy
1. Patient with genitourinary tract infection
2. Patient with severe hydronephrosis
3. Diabetic patients
4. Patient with allergic histology to alpha blockers
6. Patient with ureter strictures
Pregnant patients

Intervention groups

Group A or control group wich recieves only pain relievers
Group B wich recieves Tablet Terazosin 5mg daily and pain reliever if indicated
Group C wich recieves Tamsulosin 0.4 mg daily and a pain reliever if indicated

Main outcome variables

Colicky pain episodes, lower urinary tract symptoms, pain reliever usage, days to repel stone and complications of medical treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201209049659N1**

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

Mohsen Khalilzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3422 4704

Email address

Mohsen73maku@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-26, 1399/10/06

Expected recruitment end date

2021-02-24, 1399/12/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between efficacy of Tamsulosin and Terazosin alpha-adrenergic blockers in spontaneous passage of ureter stones after Extracorporeal Shock Wave Lithotripsy

Public title

Comparison of alpha blockers efficacy in kidney stones passage

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with lower ureter stone with minimal size of 5 millimetr Stone is radiopaque and is detectable on CT scan Patient is a candidate of Extracorporeal Shock Wave Lithotripsy

Exclusion criteria:

Patient with genitourinary tract infection Patient with severe hydronephrosis Diabetic patients Patient with allergic histology to alpha blockers Patient with ureter strictures Pregnant patients

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomisation sequence will be processed by Microsoft Excel program via (RANDBETWEEN) command

Blinding (investigator's opinion)

Single blinded

Blinding description

Tamsulosin and Terazosin tablets are indistinguishable for patients and can not be recognised by their appearance

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Tabriz Branch

Street address

No. 27 , Ghahere Ave., Danesh Street, Ardabil City

City

Tabriz

Province

East Azarbaijan

Postal code

5157944533

Approval date

2020-12-08, 1399/09/18

Ethics committee reference number

IR.IAU.TABRIZ.REC.1399.143

Health conditions studied

1

Description of health condition studied

Ureter stones

ICD-10 code

N20.1

ICD-10 code description

Calculus of ureter

Primary outcomes

1

Description

Days to repel stone, Colicky pain episodes, Lower urinary tract symptoms, Total pain reliever use dosage, Complications of drugs

Timepoint

Patient outcomes upon enrollment in the study and in the 2 weeks

Method of measurement

Patient history and ultrasound imaging

Secondary outcomes

empty

Intervention groups

1

Description

Group A or control: After extracorporeal shockwave lithotripsy, patients in this group will only receive 50 mg Diclofenac suppository in case it is needed

Category

Treatment - Drugs

2

Description

Intervention group B: After extracorporeal shockwave lithotripsy, patients in this group will receive 5 mg Terazosin tablets once daily and Diclofenac suppository in case it is needed

Category

Treatment - Drugs

3

Description

Intervention group C: After extracorporeal shockwave lithotripsy, patients in this group will receive 0.4 mg Tamsulosin tablets once daily and Diclofenac suppository in case it is needed for pain control.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabalan hospital

Full name of responsible person

Hamid deldadeh moghaddam

Street address

Basij HWY, Sabalan Hospitals

City

Ardabil

Province

Ardabil

Postal code

478- 56135

Phone

+98 45 3333 9794

Email

Shahram-Tamin@ yahoo.com

Web page address

<https://www.tamin.ir/News/Item/15265/96/15265.html>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad reza sedaghat

Street address

No. 27 , Ghahere Ave., Danesh Street, Ardabil City

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Province

Ardabil

Postal code

5861874818

Phone

+98 45 3372 2545

Email

research.iauardabil@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Mohsen Khalilzadeh

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Danesh street, ghahere Avenue no. 27

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Medical student

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Person responsible for updating data

Contact

Name of organization / entity

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only data related to outcomes will be shared

When the data will become available and for how long

Data will be accessible from 21 march 2021 onward

To whom data/document is available

independent researchers and researchers of different organisations

Under which criteria data/document could be used

No restrictions on data analysis after data is shared

From where data/document is obtainable

Mohsen Khalilzade

What processes are involved for a request to access data/document

All requests should be sent to the email address (mohsen73maku@yahoo.com) and will be responded in 2 weeks time

Comments