

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between Silodosin and Extracorporeal Shockwave Lithotripsy

Protocol summary

Study aim

To compare the effectiveness of Silodosin and extracorporeal shock wave lithotripsy (ESWL) in patients admitted for management of lower ureteric stone.

Design

Randomized Clinical Trial

Settings and conduct

The trial was double-blind and commenced at the Urology department of LUMHS, Jamshoro from August 2023 to July 2024. Blinding maintenance was ensured by using envelopes/slips that indicate only the group allocation without revealing the intervention details, keeping trial participants, data collectors, and outcome assessors blinded; additionally, interventions were designed to appear identical where feasible, such as in color, consistency, or packaging.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between the ages of 15-70 years, both gender, and having stone sizes 5-10mm in the lower ureteric region were included. Exclusion Criteria: Patients having a single functional kidney before treatment, previous ureteric surgery, ureteric stones bilaterally, stricture in the ureteric region, previous stone passage, using alpha-adrenergic receptor blockers, and pregnant women and patients who lost follow up were excluded.

Intervention groups

Group A 8 mg capsule of Silodosin was given for 28 days and once daily and advised for urine collection and discontinuation of the medication upon passage of stone, with the time and date of passage recorded. Group B underwent ESWL

Main outcome variables

Demographic and baseline data, including age, duration of symptoms, BMI, hypertensive status, and diabetes, were recorded. Baseline investigations, including a computed tomography (CT) scan of the kidneys, ureters, and bladder (KUB), were performed to measure the size of the stone. After 1 month of treatment, patients underwent computed tomography scans to detect any

residual stones or fragments in the ureter. If stones were not found, the patient was classified as stone-free.

General information

Reason for update

Acronym

SILES: Silodosin vs. ESWL for Lithiasis Evaluation Study

IRCT registration information

IRCT registration number: **IRCT20250125064509N1**

Registration date: **2025-02-06, 1403/11/18**

Registration timing: **retrospective**

Last update: **2025-02-06, 1403/11/18**

Update count: **0**

Registration date

2025-02-06, 1403/11/18

Registrant information

Name

Zakir Hussain Rajpar

Name of organization / entity

Liaquat University of Medical and Health Sciences

Country

Pakistan

Phone

+92 300 9370622

Email address

zrajpar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-01, 1402/05/10

Expected recruitment end date

2024-06-30, 1403/04/10

Actual recruitment start date

2023-08-01, 1402/05/10

Actual recruitment end date

2024-06-30, 1403/04/10

Trial completion date

2024-06-30, 1403/04/10

Scientific title

Comparison between Silodosin and Extracorporeal Shockwave Lithotripsy

Public title

Comparison between Silodosin and Extracorporeal Shockwave Lithotripsy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages of 15-70 years Both gender Stone sizes 5-10mm in the lower ureteric region

Exclusion criteria:

Single functional kidney before treatment Previous ureteric surgery Ureteric stones bilaterally Stricture in the ureteric region Previous stone passage, Using alpha-adrenergic receptor blockers Pregnant women Patients who lost follow up

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **192**

Actual sample size reached: **192**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided into two groups by lottery method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding maintenance was ensured by using envelopes/slips that indicate only the group allocation without revealing the intervention details, keeping trial participants, data collectors, and outcome assessors blinded; additionally, interventions was designed to appear identical where feasible, such as in color, consistency, or packaging.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Liaquat University of Medical and Health Sciences, Jamshoro, Hyderabad.

Street address

Liaquat University of Medical and Health Sciences

City

Jamshoro, Hyderabad

Postal code

76080

Approval date

2023-02-04, 1401/11/15

Ethics committee reference number

LUMHS/REC/500

Health conditions studied**1****Description of health condition studied**

Lower ureteric stone

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Stone Clearance Rate

Timepoint

After 1 month of treatment

Method of measurement

computed tomography scans to detect any residual stones or fragments in the ureter

Secondary outcomes**1****Description**

occurrence of complications like Pain, Bleeding, Dizziness, Postural hypotension, retrograde ejaculation

Timepoint

1 month after treatment

Method of measurement

Patients complain and and examination

Intervention groups**1****Description**

Intervention group: Shock wave lithotripsy

Category

Treatment - Surgery

2**Description**

Control group: Sildosin
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Liaquat university of medical and health sciences,
Jamshoro

Full name of responsible person

Zakir Hussain Rajpar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Liaquat University of Medical and Health Sciences

Full name of responsible person

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Street address

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Grant name

Grant code / Reference number

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

No

Title of funding source

Self

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Liaquat University of Medical and Health Sciences

Full name of responsible person

Zakir Hussain Rajpar

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidential data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available