Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 basekine 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
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+92 300 9370622
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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 ejacualation

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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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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Position
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Other areas of specialty/work
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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