

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The efficacy of intra-pyelocaliceal injection of dexamethasone in trans ureteral lithotripsy on postoperative analgesics consumption: A triple-blinded randomized clinical trial

Protocol summary

Study aim

Investigation of the effect of dexamethasone administration in the pyelocaliceal space of the kidney in transurethral lithotripsy (TUL) on postoperative analgesic consumption.

Design

Randomized, parallel-group trial with blinded outcome assessment, and data analysis. A centralized computer randomization system was used.

Settings and conduct

The urologist injected one ampoule of dexamethasone into the pyelocaliceal space for patients in the intervention group using a ureteroscope before double J stent placement. In the control group, no drug was injected into the pyelocaliceal space. After recovery and transferring the patients to the ward, based on the patient's needs and the pain intensity stated by the patients, analgesics drug consumption was recorded. Follow-up of patients continued until discharge from the hospital. All patients, outcome assessors, and caregivers were blinded to the intervention group. The study was conducted in the urology department and operating room of Razi Medical Education Hospital in Birjand city, South Khorasan province, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria included patients with ureteral stones (requiring TUL operation), ages over 18 years, and written consent to participate in the study. Exclusion criteria included pregnancy, single kidney, urinary tract infection, drug or psychotropic addiction, ureteral rupture, use of ureteroscope and stents of different sizes, and history of sensitivity to dexamethasone.

Intervention groups

The urologist surgeon injected one ampoule of dexamethasone (8mg/2mL) into the pyelocaliceal space for patients in the intervention group using a ureteroscope and then placed a double J. In the control

group, no dexamethasone ampoule or other drugs were injected into the pyelocaliceal space before placing the double J stent.

Main outcome variables

Postoperative analgesics consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210509051237N1**

Registration date: **2023-09-27, 1402/07/05**

Registration timing: **prospective**

Last update: **2023-09-27, 1402/07/05**

Update count: **0**

Registration date

2023-09-27, 1402/07/05

Registrant information

Name

Ramin Honarmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3222 4710

Email address

raminhonarmand@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of intra-pyelocaliceal injection of dexamethasone in trans ureteral lithotripsy on postoperative analgesics consumption: A triple-blinded randomized clinical trial

Public title

Effect of Dexamethasone injection on trans ureteral lithotripsy postoperative pain

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with ureteral stones (requiring TUL operation)
Ages over 18 years written informed consent to participate in the study

Exclusion criteria:**Age**From **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample sizeTarget sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

In addition to the centralized computer randomization system, the method of simple randomization was used to allocate patients to either the control or intervention group. The randomization unit for this study was patients who met the eligibility criteria. No cluster randomization was used in this trial. To create a random sequence for the study, the study team used a random number generator built into the REDCap Cloud system. To maintain allocation concealment, the allocation sequence was kept hidden from the study team until the point of randomization. This was achieved through the use of a centralized automated system, which prevented study personnel from predicting the allocation sequence or knowing the allocation of any individual patient before randomization.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In addition to randomization and allocation concealment, this study also utilized a triple-blinding process. To achieve participant blinding, both the intervention and

control groups received an identical-appearing treatment, they underwent the same type of surgery, and stents were implanted for both groups; However, all patients were aware that they were participating in a study and received the main treatment. Study personnel were also blinded to the treatment allocation. The healthcare providers, researchers, and study coordinators involved in any aspect of the study conduct were unaware of the treatment assignments. Lastly, outcome assessors were blinded by having a separate team of blinded assessors who were not involved in patient care and who performed the outcome assessments. Only the urologist and anesthesiologist were aware of each patient's group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853076

Approval date

2021-04-19, 1400/01/30

Ethics committee reference number

IR.BUMS.REC.1400.026

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

Calculus of ureter

ICD-10 code

N20.1

ICD-10 code description

Calculus of ureter

2**Description of health condition studied**

Postoperative pain of ureteroscopy

ICD-10 code

N99

ICD-10 code description

Intraoperative and postprocedural complications and disorders of genitourinary system, not elsewhere classified

Primary outcomes

1

Description

Postoperative analgesics consumption

Timepoint

After recovery and transferring the patients to the ward until discharge

Method of measurement

The amount of analgesics received by the patient based on his needs, recorded by the nurses

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the urologist surgeon injected one ampoule of dexamethasone (Alborzdarou) (8mg/2mL) into the pyelocaliceal space for patients in the intervention group using a 9.8 French semi-rigid ureteroscope and then placed a double-J 4.7 French stent at 28 cm (Goharshafa).

Category

Prevention

2

Description

Control group: no dexamethasone or other drugs were injected into the pyelocaliceal space before placing the double-J stent.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Ramin Honarmand

Street address

Razi hospital, Ghaffari Ave.

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Email

razihospital@bums.ac.ir

Web page address

<https://razi.bums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mohamadreza Miri

Street address

Research and education department, Birjand University of Medical Sciences, Ghaffari Ave.

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research@bums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Ramin Honarmand

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

All data after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

Researchers in scientific and academic institutions

Under which criteria data/document could be used

Analyzing the data is allowed if it is part of a larger study.

From where data/document is obtainable

To receive data or documents, you can send your request via email to one of the following people: 1. Dr. Ramin Honarmand, the main researcher ramin_h_1360@yahoo.com 2. Hadis Enayati, a member of the research team hadissenayati@gmail.com

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

The submitted request will be reviewed within a week and the data file and documents will be sent via email within a maximum of 2 weeks.

Comments