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 size
Target 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 uretroscopy
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.
City
Birjand
Province
South Khorasan
Postal code
9717844471
Phone
+98 56 3162 6000
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.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3238 1200
Email
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
Street address

No. 9, No 8/6 Alley, Taleghani 8 St, Taleghani Ave

City
Birjand

Province
South Khorasan

Postal code
9817713881

Phone
+98 56 3222 4710

Fax

Email
raminhonarmand@bums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Ramin Honarmand

Position
Assistant professor

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Person responsible for updating data

Contact

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Birjand University of Medical Sciences

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Ramin Honarmand

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