

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Comparison of clinical manifestations of DJ adjustment in ureteral lumen with routine technique

Protocol summary

Study aim

The comparison of clinical manifestations of DJ adjustment in ureteral lumen with routine technique

Design

Two arm parallel randomized clinical trial, double blind in which the patients are divided in two group of 1 or 2 according to the number that will be picked up by patients and none of the patients and evaluator are not aware of allocation group.

Settings and conduct

In the Imam Reza Hospital of Kermanshah University of Medical Sciences during one year, 110 patients who require TUL and DJ insertion, will be allocated by a simple randomization in two groups of 1 and 2. In the group 1 following TUL the DJ will adjust routinely and in the group 2 the distal tail will be fixed in UVJ.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1.The first time TUL 2.Age of 18-50 years 3. Ureter stone smaller than 15mm 4.No significant residual fragment in ureter (< 4 mm) 5.No bladder stone 6.Unilateral ureteral stone 7.No additional intervention be required following DJ insertion 8.Negative Urine Culture 9.IIEF-5> 21 Exclusion criteria: 1.History of urinary tract surgery 2.BPH 3.Long term LUTS 4.Coagulopathies 5.Anticoagulant drugs users 6.Advanced cardiac or hepatic disorders 7.Chronic consumption of NSAIDs or α -blockers 8.Pregnancy 9.IPSS > 7

Intervention groups

Intervention Group: following TUL, the distal tail of DJ adjusts in the ureter right in UVJ. Control Group: following TUL, the distal tail of DJ adjusts in the bladder.

Main outcome variables

Urinary Symptom Score; Existence of Pain (%); Body Pain Score; VAS of Pain; General Health Score; Quality of Work Score; Quality of Sex Score; Quality of Life Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180725040589N2**

Registration date: **2019-07-01, 1398/04/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-01, 1398/04/10**

Update count: **0**

Registration date

2019-07-01, 1398/04/10

Registrant information

Name

Mahmoudreza Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 6337

Email address

drmoradi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-21, 1398/02/31

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of clinical manifestations of DJ adjustment in ureteral lumen with routine technique		Kermanshah, Shahid Beheshti Blvd. Central Building of University, Postal code: 6715847141	
Public title	the effect of route of ureteral stent adjustment and subsequent effects	City	Kermanshah
Purpose	Treatment	Province	Kermanshah
Inclusion/Exclusion criteria	Inclusion criteria: The first time TUL Age of 18-50 years Ureteral stone smaller than 15mm No significant residual fragment in ureter (> 4 mm) No bladder stone Unilateral ureteral stone No additional intervention be required following DJ insertion Negative Urine Culture IIEF-5> 21 Exclusion criteria: History of urinary tract surgery BPH Long term LUTS Coagulopathies Anticoagulant drugs users Advanced cardiac or hepatic disorders Chronic consumption of NSAIDs or α-blockers pregnancy IPSS > 7	Postal code	6715847141
Age	From 18 years old to 50 years old	Approval date	2019-05-19, 1398/02/29
Gender	Both	Ethics committee reference number	IR.KUMS.REC.1398.197
Phase	N/A	Health conditions studied	
Groups that have been masked	- Participant - Outcome assessor	1	
Sample size	Target sample size: 110	Description of health condition studied	
Randomization (investigator's opinion)	Randomized	Ureteral Stone	
Randomization description	by picking up a piece of paper in a box by participant containing the same numbers of 1 (group one that distal tail of double J adjust routinely) and 1 (group 2 that distal tail of DJ is adjust in ureter in vesicoureteral junction)	ICD-10 code	N13.2
Blinding (investigator's opinion)	Double blinded	ICD-10 code description	Hydronephrosis with renal and ureteral calculous obstruction
Blinding description	None of patients and evaluator are aware of the groups	Primary outcomes	
Placebo	Not used	1	
Assignment	Parallel	Description	
Other design features		Urinary Symptom Score	
Secondary Ids		Timepoint	Before DJ insertion, first and forth weeks after DJ adjustment and a week after DJ removal
empty		Method of measurement	By USSQ
Ethics committees		2	
1		Description	
Ethics committee		Existence of Pain (%)	
Name of ethics committee	Ethics Committee of Kermanshah University of medical Sciences	Timepoint	Before DJ insertion, first and forth weeks after DJ adjustment and a week
Street address		Method of measurement	By USSQ
		3	
		Description	
		Body Pain Score	
		Timepoint	Before DJ insertion, first and forth weeks after DJ adjustment and a week
		Method of measurement	By USSQ
		Secondary outcomes	
		empty	

Intervention groups

1

Description

Intervention group: following TUL the distal tail of DJ adjusts in the ureter right in UVJ.

Category

Treatment - Surgery

2

Description

Control group: following TUL the distal tail of DJ adjusts in the bladder

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Kermanshah University of Medical Sciences

Full name of responsible person

Mahmoudreza Moradi

Street address

Kermanshah, Shahid Beheshti Blvd., Central Building of University

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3835 8258

Email

drmmoradi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Mahmoudreza Moradi

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

5

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

Kermanshah University of Medical Sciences

Full name of responsible person

Mahmoudreza Moradi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

All the Gathered Data

**When the data will become available and for how
long**

Following the end of study

To whom data/document is available

The Academic Resaerchers

Under which criteria data/document could be used

In order to promote our Knowledge

From where data/document is obtainable

By Mailing to corresponding Researcher

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

After Receiving the apply mail it will be planed.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

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Latest degree

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