Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Double J Insertion with Nephrostomy in Pelvic Trauma Management After Percutaneous nephrolithotomy

Protocol summary

Study aim
Aim were Comparison of Double J Insertion with Nephrostomy in Pelvic Trauma Management After Percutaneous nephrolithotomy

Design
This evaluation is a phase 4 clinical trial, patients diagnosed with renal stone having PCNL and having trauma to the pelvis were considered as the study group, in this study 60 patients who met the inclusion criteria were chosen. Patients were non randomly divided into two groups by non-blocking method, 28 patients in the double J group and 30 patients in the nephrostomy group. Patients were evaluated 2 weeks after surgery.

Settings and conduct
This clinical trial study was performed at Shahid Hashemi Nejad Hospital in Tehran.

Participants/Inclusion and exclusion criteria
Patients with pelvic trauma and consent to participate in the study were enrolled to study, also patients with a history of kidney stone surgery, bleeding disorders, and taking an anticoagulant drug were excluded from study.

Intervention groups
In the first group, patients were treated with double J stent for treatment and in the second group, nephrostomy was used.

Main outcome variables
Urinary residual volume; fever

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191230045956N1**
Registration date: **2020-02-08, 1398/11/19**
Registration timing: **retrospective**

Last update: **2020-02-08, 1398/11/19**
Update count: **0**

Registration date
2020-02-08, 1398/11/19

Registrant information

Name
mohammad kolbadinezhad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3455 2628

Email address
mohammad_kolbadinezhad@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-05-21, 1396/02/31

Expected recruitment end date
2017-12-21, 1396/09/30

Actual recruitment start date
2017-05-21, 1396/02/31

Actual recruitment end date
2018-01-09, 1396/10/19

Trial completion date
2018-01-09, 1396/10/19

Scientific title
Comparison of Double J Insertion with Nephrostomy in Pelvic Trauma Management After Percutaneous nephrolithotomy

Public title
Comparison of Double J with Nephrostomy in Pelvic Trauma Management

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pelvic trauma Consent to participate in the study
Exclusion criteria:
A history of kidney stone surgery Bleeding disorders
Taking an anticoagulant drug

Age
No age limit

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **60**
Actual sample size reached: **58**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical
Street address
Next to Milad tower, Hammat highway.
City
Tehran
Province
Tehran
Postal code
1799737737

Approval date
2018-03-03, 1396/12/12

Ethics committee reference number
IR.IUMS.FMD.REC.1396.9311254005

Health conditions studied

1

Description of health condition studied
Calculus of kidney

ICD-10 code
N20

ICD-10 code description
Calculus of kidney and ureter

Primary outcomes

1

Description
Urinary residual volume

Timepoint
2 weeks after surgery

Method of measurement
Using ultrasound

2

Description
Fever

Timepoint
2 weeks after surgery

Method of measurement
Based on clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group of patients, double J stent were used.

Category
Treatment - Surgery

2

Description
Intervention group: This group of patients were underwent nephrostomy.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Hashemi Nejad Hospital
Full name of responsible person
Mohammad Kalbadi Nejad
Street address
Hashemi Nejad Hospital, Valinezhad St, Tehran
City
Tehran
Province
Tehran
Postal code
1969714713
Phone
+98 21 8116 1811
Email

mohammad_kolbadinezhad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Morteza Naserbakht
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86709
Email
ivco@iums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mohammad Kalbadi Nejad
Position
Resident of urology
Latest degree
Specialist
Other areas of specialty/work
Urology
Street address
Hashemi Nejad Hospital, Valinezhad St, Tehran
City
Tehran
Province
Tehran
Postal code
1969714713
Phone
+98 21 8116
Email
mohammad_kolbadinezhad@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammad Kalbadi Nejad
Position
Resident of urology
Latest degree
Specialist
Other areas of specialty/work
Urology
Street address
Hashemi Nejad Hospital, Valinezhad St, Tehran
City
Tehran
Province
Tehran
Postal code
1969714713
Phone
+98 21 8116
Email
mohammad_kolbadinezhad@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammad Kalbadi Nejad
Position
Resident of urology
Latest degree
Specialist
Other areas of specialty/work
Urology
Street address
Hashemi Nejad Hospital, Valinezhad St, Tehran
City
Tehran
Province
Tehran
Postal code
1969714713
Phone
+98 21 8116
Email
mohammad_kolbadinezhad@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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