

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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

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1969714713

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+98 21 8116 1811

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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

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Tehran

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Tehran

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1449614535

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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

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Person responsible for updating data

Contact

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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