Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

evaluating the efficacy of transcatheter angioembolization for renal trauma following Percutaneous Nephrolithotomy

Protocol summary

Study aim

1- evaluating the efficacy of transcatheter angioembolization for renal trauma following Percutaneous Nephrolithotomy 2- evaluating complications of transcatheter angioembolization for renal trauma following Percutaneous Nephrolithotomy

Design

interventional study without control group, on 60 patients

Settings and conduct

patients who had severe hematuria after PCNL at Sina hospital. inclusion criteria: persistent hemorrhagia after nephrolithotomy, hemoglobin decrease, delayed hemorrhagia which is unresponsive to conservative therapy, exclusion criteria: persistent hypotension,allergy to contrast, patient non consent, coagulopathy, contraindication for contrast injection before angiography, serum Cr, urine analysis and culture test was done and doppler ultrasound of kidneys was performed. ultrasound findings such as pseudoaneurysm , AVF and hematoma was recorded. after patients informed consent, angiography and angioembolization was done. the patient follow up will be done considering hematuria cessation, need for transfusion or surgery and procedure complications such as renal artery damage, creatinin rise and renal abcess

Participants/Inclusion and exclusion criteria

patients who had severe hematuria after Percutaneous Nephrolithotomy (PCNL) at Sina hospital. inclusion criteria: persistent hemorrhagia after nephrolithotomy, hemoglobin decrease, delayed hemorrhagia which is unresponsive to conservative therapy, exclusion criteria: persistent hypotension,allergy to contrast, patient non consent, coagulopathy, contraindication for contrast injection

Intervention groups

Angioembolization with coil was done for the patients who had severe or persistent hematuria after PCNL

Main outcome variables

hematuria cessation, probable complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230715058782N1**
Registration date: **2023-08-05, 1402/05/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-05, 1402/05/14**
Update count: **0**

Registration date

2023-08-05, 1402/05/14

Registrant information

Name

Mohammad Ashouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2606

Email address

m-ashouri@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-01, 1402/05/10

Expected recruitment end date

2024-07-25, 1403/05/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
evaluating the efficacy of transcatheter angioembolization for renal trauma following Percutaneous Nephrolithotomy

Public title
Efficacy of Angoembolization on post PCNL persistent Hematuria

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Persistent Hematuria after PCNL Hemoglobin drop needing transfusion Delayed persistent hematuria
Exclusion criteria:
hypotension allergy to iodine contrast coagulopathy contraindication for iodine contrast patient refusal

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Surgery Ward 3&4, Imam khomeini Hospital complex, Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱

Approval date
2023-06-06, 1402/03/16

Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1402.030

Health conditions studied

1

Description of health condition studied
injury of renal blood vessels post PCNL

ICD-10 code
S35.4

ICD-10 code description
Injury of renal blood vessels

Primary outcomes

1

Description
Hematuria cessation

Timepoint
daily control after angioembolization

Method of measurement
urine appearance

2

Description
serum creatinine

Timepoint
before and 2days after angioembolization

Method of measurement
laboratory

3

Description
hemoglobin

Timepoint
before and daily after angioembolization

Method of measurement
Laboratory

4

Description
Packed RBC need for hemodynamic stability

Timepoint
before and after angioembolization

Method of measurement
transfused Packed cell

5

Description
Angiographic complications

Timepoint
After angioembolization

Method of measurement
complications related to angioembolization detected by

sonography

6

Description
Need to operation for bleeding control
Timepoint
daily after angioembolization
Method of measurement
Operation for control of hematuria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patient who underwent PCNL and suffer from persistent severe hematuria needing transfusion and patient with delayed hematuria without proper response to conservative treatments are included and undergo transcatheter angiography and if vascular injury is detected angioembolization with coil (COOK Medical) will perform to stop blood flow to the injured vessel
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Mohammad Ashouri
Street address
Surgery ward 3&4, Imam khomeini hospital complex, Keshavarz blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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qos ave. Keshavarz blvd.
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ashouri
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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inquiries

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Person responsible for updating data

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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