

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

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

Protocol summary

hematuria cessation, probable complications

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

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

Akbar Fotouhi

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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

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Specialist

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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