

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of preoperative intravenous mannitol injection in reducing acute kidney injury following percutaneous nephrolithotomy

Protocol summary

Study aim

Prevention of reduction in renal function after percutaneous nephrolithotomy. Improvement in renal function after percutaneous nephrolithotomy. To compare complications of percutaneous nephrolithotomy in case and control groups

Design

Randomised clinical trial including 75 patients in 2 parallel case and control groups ; triple blinded (patients , surgeon and data analyzer were all blind), Randomised with balanced block randomization table.

Settings and conduct

150 patients 18-75 years of age who are candidates for percutaneous nephrolithotomy (PCNL) referring to Hasheminejad Kidney Center will be randomly divided into 2 groups of 75 patients. In the intervention group 15 minutes before surgery 25 g intravenous mannitol will be injected. In the control group no mannitol will be injected. Glomerular filtration rate (GFR) will be measured using the cockroft gault equation based on creatinine levels on the day before surgery, 6 hours after surgery, 1, 2, and 14 days after surgery. In this study, the surgeon, the static analyzer, the data collector, and the patients will be blinded to injection of mannitol.

Participants/Inclusion and exclusion criteria

Patients candiate for percutaneous nephrolithotomy between 18 to 75 years old; without history of deep vein thrombosis, emboli, brain edema, high intracranial pressure, digoxin user, and lithium user, coagolopathies, Heart failure

Intervention groups

In case group, 15 minutes before percutaneous nephrolithotomy, 25 grams of mannitol solution will be injected intravenously. In control group, non mannitol serum will be injected.

Main outcome variables

Glomerular filtration rate changes, Serum hemoglobin level changes, Complications of the surgery in both groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200110046073N1**

Registration date: **2020-03-01, 1398/12/11**

Registration timing: **prospective**

Last update: **2020-03-01, 1398/12/11**

Update count: **0**

Registration date

2020-03-01, 1398/12/11

Registrant information

Name

Mohammadmehdi Atarod

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2289 2684

Email address

atarod.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-04, 1398/12/14

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 effect of preoperative intravenous mannitol injection in reducing acute kidney injury following percutaneous nephrolithotomy

Public title

The effect of preoperative intravenous mannitol injection in reducing acute kidney injury following percutaneous nephrolithotomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with renal stone greater than 20 mm in diameter who are candidates for percutaneous nephrolithotomy. Patients with proximal ureter stone greater than 20 mm in diameter who are candidates for percutaneous nephrolithotomy.

Exclusion criteria:

Heart failure History of lung embolism History of deep vein thrombosis History of brain edema History of intracranial hemorrhage Respiratory edema Anuria History of digoxin consumption History of Lithium consumption History of allergy to mannitol Electrolyte imbalance Coagulopathies

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

According to a Balance block randomization table prepared for 150 patients with statistical software, 75 patients will be in case and the rest will be in the control group randomly. This table will be just given to the anesthesiologist who is the only person who knows the patient group. All patients who have the criteria of this study will be placed in one of the case or control group respectively as they come to the operating room according to the Balance block randomization table by the anesthesiologist. Each patient has a form with a number at the top which does not show the group of patient. All the data except for the group of the patients will be inserted to an SPSS form by one person and the group will be inserted in a 0 and 1 manner in another SPSS form by another person and then will be copied to the first SPSS form. Data analyser will not be informed of the group of patients and will know them as group 0 and 1. After analysis finished, we will have access to the type of 0 and 1 group according to the person who

inserted the data of group type in the SPSS form.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients, data collector and analyzer, and the researcher will be all blinded to injection of mannitol. It will be done according to the balance block randomization table by Anesthesiologist.

Placebo

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 Sciences

Street address

Vanak sq- Valiasr st- Valinejad st- Hasheminejad Kidney Center Hospital

City

Tehran

Province

Tehran

Postal code

1969714713

Approval date

2020-02-24, 1398/12/05

Ethics committee reference number

IR.IUMS.REC.1398.1221

Health conditions studied

1

Description of health condition studied

Acute kidney injury, Renal stone, Percutaneous nephrolithotomy (PCNL)

ICD-10 code

N99.0

ICD-10 code description

Postprocedural (acute) (chronic) kidney failure

Primary outcomes

1

Description

Post percutaneous nephrolithotomy glomerular filtration rate changes

Timepoint

The day before surgery, 6 hours after surgery, 1, 2, and 14 days after surgery

Method of measurement

cockroft gault equation (based on serum creatinine level)

Secondary outcomes**1****Description**

Post operative hemoglobin changes

Timepoint

The day before surgery, 6 hours after surgery, 1, 2, and 14 days after surgery

Method of measurement

Complete blood count

2**Description**

Post operative infection

Timepoint

The day before surgery, 6 hours after surgery, 1, 2, and 14 days after surgery

Method of measurement

Thermometer

Intervention groups**1****Description**

Intervention group: Interavenous injection of 25 grams of mannitol (125 cc of 20% mannitol Serum) in 75 patients candidated for percutaneous nephrolithotomy, 15 minutes before surgery

Category

Prevention

2**Description**

Control group: Interavenous injection of 125 cc of Non mannitol Serum in 75 patients candidated for percutaneous nephrolithotomy, 15 minutes before surgery.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hasheminejad Kidney Center

Full name of responsible person

Mohammadmehdi Atarod

Street address

Vanak Sq- Valiasr St- Valinejad St- Hasheminejad Kidney Center Hospital

City

Tehran

Province

Tehran

Postal code

1969714713

Phone

+98 21 8864 4441

Email

dr.atarod@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Seyyed Abbas Motevalian

Street address

Hemmat Highway- Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Email

motevalian.a@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

Kaveh Mehravaran

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Vanak sq- Valiasr st- Valinejad st- Hasheminejad
Kidney Center Hospital

City

Tehran

Province

Tehran

Postal code

1969714713

Phone

+98 21 8864 4441

Email

Mehravarankaveh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kaveh Mehravarn

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Vanak sq- Valiasr st- Valinejad st- Hasheminejad
Kidney Center Hospital

City

Tehran

Province

Tehran

Postal code

1969714713

Phone

+98 21 8864 4441

Email

Mehravarankaveh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

MohammadMehdi Atarod

Position

Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Vanak sq- Valiasr st- Valinejad st- Hasheminejad
Kidney Center Hospital

City

Tehran

Province

Tehran

Postal code

1969714713

Phone

+98 21 8864 4441

Email

dr.atarod@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can potentially be shared after hiding patients
identity

When the data will become available and for how long

18 months after article publication, data is available

To whom data/document is available

Only for researches in universities and academic
institutions

Under which criteria data/document could be used

No other condition is needed

From where data/document is obtainable

Mohammadmehdi Atarod 00989120233308
dr.atarod@gmail.com

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

After receiving an email based on the need to access the
data of this article, respond will be sent within 30 work
days

Comments