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)
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+98 21 2289 2684
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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 candidated for percutaneous nephrolithotomy. Patients with proximal ureter stone greater than 20 mm in diameter who are candidated 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 Electrolite imbalance Coagolopathies

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 the 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 finnished, 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
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Tehran
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1969714713
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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
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1449614535
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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
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
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Latest degree
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Other areas of specialty/work
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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