

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### comparison of efficacy and adverse effects of sterile water and normal saline for irrigation fluid in percutaneous nephrolithotripsy(PCNL)

#### Protocol summary

2013-02-11, 1391/11/23

#### Summary

Introduction and objectives. The irrigation fluid that routinely used during PCNL has systemic absorption and may lead to hyponatremia or hemolysis. Aim of this study is comparing efficacy and adverse effect of sterile water and normal saline as an irrigation fluid in percutaneous nephrolithotomy (PCNL). Material and methods: ninety four adult patients older than 18 years old with renal or upper ureteral stones that candidate for PCNL after taking informed consent form and approval of ethic committee of Yasuj University of Medical Sciences randomly allocated in two groups. Patient with ASA score 3 and 4 and history of hemolysis excluded from study. From all patient serum base laboratory and serum electrolyte was taken. Then under spinal anesthesia PCNL was done with fluoroscope guidance in prone position by standard method with use of normal saline in first group. In second group PCNL with fluoroscope guidance in standard method with use of sterile water was done too. Preoperative, intraoperative and postoperative variables such as serum sodium, potassium and haptoglobin, cost of irrigation fluid, duration of surgery, pulmonary and cardiovascular complications will be compare between two groups. Data will be collected by observation and questionnaire and will compare with statistical tests.

#### Registrant information

##### Name

Sadrollah Mehrabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3334 6070

##### Email address

dr.mehrabi@yums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Yasuj University of Medical Sciences

#### Expected recruitment start date

2011-06-01, 1390/03/11

#### Expected recruitment end date

2013-03-01, 1391/12/11

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

comparison of efficacy and adverse effects of sterile water and normal saline for irrigation fluid in percutaneous nephrolithotripsy(PCNL)

#### Public title

sterile water and normal saline in PCNL

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

inclusion and exclusion criteria are includes (Inclusion criteria:Age>18 years old ,patients with renal or upper ureteral stone larger than 20 millimeter candidate for

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201212291323N5**

Registration date: **2013-02-11, 1391/11/23**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

percutaneous nephrolithotripsy , Exclusion criteria:  
patients with urinary stone younger than 18 years old  
,patients with azotemia.uncontrolled coagulopathy,active  
infection,history of hemolysis,any contraindication for  
general or spinal anesthesia,COPD,ASA score 3 and 4 )

#### Age

From **18 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **94**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single 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 Yasuj University of Medical  
Sciences

##### Street address

Motahari street,yasuj university of medical sciences

##### City

Yasuj

##### Postal code

#### Approval date

2011-03-01, 1389/12/10

#### Ethics committee reference number

23/8/2876/پ

## Health conditions studied

### 1

#### Description of health condition studied

Calculus of kidney with calculus of ureter

#### ICD-10 code

N20.2

#### ICD-10 code description

Calculus of kidney with calculus of ureter

## Primary outcomes

### 1

#### Description

cheke of serum electrolytes and hemolysis in  
percutaneous nephrolithotripsy

#### Timepoint

Before operation and 6 hour after operation

#### Method of measurement

checking Na,K,and serum haptoglobin before and 6 hour  
operation

## Secondary outcomes

### 1

#### Description

development of any cardiovascular or pulmonary  
complications

#### Timepoint

during operation to one week later

#### Method of measurement

report of patients and observation with examination lung  
and heart of of patients pulse oximetry during  
operation,and check of lower limb pulses

## Intervention groups

### 1

#### Description

Case group :use of sterile water as an irrigation fluid  
during PCNL operation

#### Category

Treatment - Surgery

### 2

#### Description

control group :use of normal saline as an irrigation fluid  
during PCNL operation

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shaheed Behehti Hospital

##### Full name of responsible person

Dr Sadrollah Mehrabi

##### Street address

Shaheed Beheshti hospital, Montazeri street,Yasuj

##### City

Yasuj

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Deputy of information and Research , Yasuj University of Medical Science

**Full name of responsible person**

Dr Mehdi Akbartabar

**Street address**

Motahari street,Yasuj University of Medical Sciences,

**City**

Yasuj

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Deputy of information and Research , Yasuj University of Medical Science

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Social Health Determinant of research center,Yasuj university of medical science

**Full name of responsible person**

Dr Sadrollah Mehrabi

**Position**

Professor,Chairman of surgery,Fellowship of Endourology, Urology Department, Yasuj University of Med

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## Person responsible for scientific inquiries

#### Contact

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**Full name of responsible person**

Dr Sadrollah Mehrabi

**Position**

chairman of surgery,professor

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## Person responsible for updating data

#### Contact

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, Fellowship of Endourology, Urology Department, Yasuj University of Medical Science

**Full name of responsible person**

Dr Sadrollah Mehrabi

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chairman of surgery,professor

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*