

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

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Iran (Islamic Republic of)

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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 haptoglobulin 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,

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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 updating data

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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