

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of hemodynamic, serum sodium and potassium changes within 24 h after percutaneous nephrolithotripsy surgery

Protocol summary

Summary

The aim of this study is to determine and compare the serum sodium and potassium levels as well as hemodynamic changes during and within 24 hours after the percutaneous nephrolithotomy. The inclusion criteria are the age between 15 to 65 years, having normal levels of sodium and potassium, having a kidney stone with a diameter greater than 2 cm and having 1 and 2 risk of anesthesia. Exclusion criteria include having histories of hypertension, diabetes mellitus, ischemic heart disease, renal failure, hyponatremia and hypokalemia and using drugs that affect serum electrolyte. This study is a before and after intervention. Sixty three patients who have the mentioned criteria are recruited. Intervention: During the procedure, intravenous normal saline (0.9%) is infused. After insertion of a urinary catheter in lithotomic situation, the patient is placed in abdomen supine position. Distilled water is used for renal washing in above procedure. The primary outcomes include measuring the patients' serum levels of sodium and potassium at study recruitment, before renal washing with distilled water, every 60 minutes during washing, after the end of the operation and during the 24 hours post-operation. The secondary outcomes include the measurements of systolic and diastolic blood pressure, percent of arterial blood oxygen saturation and heart rate during the mentioned intervals.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031116948N1**

Registration date: **2014-06-22, 1393/04/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-06-22, 1393/04/01

Registrant information

Name

Leila Shaddel

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 914 455 8145

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-07-01, 1393/04/10

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of hemodynamic, serum sodium and potassium changes within 24 h after percutaneous nephrolithotripsy surgery

Public title

Evaluation of the changes of blood pressure, serum sodium and potassium levels after percutaneous nephrolithotripsy surgery

Purpose

Treatment

Inclusion/Exclusion criteria
 The inclusion criteria are the age between 15 to 65 years, having normal levels of sodium and potassium, having a kidney stone with a diameter greater than 2 cm and having 1 and 2 risk of anesthesia. Exclusion criteria include having histories of hypertension, diabetes mellitus, ischemic heart disease, renal failure, hyponatremia and hypokalemia and using drugs that affect serum electrolyte. Also, the change in the performing procedure that lead to more absorption of washing liquid is another exclusion criteria.

Age
 From **15 years** old to **65 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **63**

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

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences,
 Golestan Ave, Ahvaz, Iran

City

Ahvaz

Postal code

Approval date

2014-01-21, 1392/11/01

Ethics committee reference number

ajums.REC.1393030

Health conditions studied

1

Description of health condition studied

Calculus of kidney

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

serum level of sodium

Timepoint

before, every 60 minutes during intervention, after the end of the intervention and during the 24 hours post intervention

Method of measurement

meq/L, Laboratory kit

2

Description

serum level of potassium

Timepoint

before, every 60 minutes during washing, after the end of the intervention and during the 24 hours post intervention.

Method of measurement

meq/L- Laboratory kit

Secondary outcomes

1

Description

systolic blood pressure

Timepoint

before, every 60 minutes during intervention, after the end of the intervention and during the 24 hours post intervention

Method of measurement

mmHg, by using blood pressure measurement device

2

Description

Diastolic blood pressure

Timepoint

before, every 60 minutes during intervention, after the end of the intervention and during the 24 hours post intervention

Method of measurement

mmHg, by using blood pressure measurement device

3

Description

percent of arterial blood oxygen saturation

Timepoint

before, every 60 minutes during intervention, after the end of the intervention and during the 24 hours post intervention

Method of measurement
Percent, by laboratory test

4

Description

Heart rate

Timepoint

before, every 60 minutes during intervention, after the end of the intervention and during the 24 hours post intervention

Method of measurement

the number of heartbeat per minute, by hemodynamic monitoring device

Intervention groups

1

Description

The intervention is Percutaneous nephrolithotomy (PCNL), a surgery that is used for the treatment of the kidney stones with large diameter. During this procedure, normal saline as well as distilled water are used for continuous renal washing. During PCNL, intravenous normal saline (0.9%) is infused. After insertion of a urinary catheter in lithotomy situation, the patient is placed in abdomen supine position. Distilled water is used for renal washing in above procedure.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Dr. Amir Salari

Street address

Emam Khomeini Hospital, Emam Khomeini Ave, Ahvaz, Iran

City

Ahvaz

2

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Dr. Amir Salari

Street address

Golestan Hospital, Golestan St, Ahvaz, Iran

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Nader Saki

Street address

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Ave, Ahvaz, Iran

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Amir Salari

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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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

Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Leila Shaddel

Position

Resident of Anesthesiology