

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of hemoglobin drop after tubeless percutaneous nephrolithotomy with flank compression on 0,3,7 minutes, aclinical trial

Protocol summary

Study aim

Determination of hemoglobin drop in the first and second day after tubeless percutaneous nephrolithotomy surgery postoperative period in patients who had abdominal flank for 3 and 7 minutes.

Design

Quasi-experimental with control group, with parallel group, randomized controlled trials, applied clinical trials

Settings and conduct

The patients who had study conditions in Hashemi nejad kidney center in Tehran will undergo at the tubeless percutaneous nephrolithotomy surgery with tubeless method, and if the operation finishes without the use of nephrostomy tube enter to the study, then the patient will randomly assigned to three flanker compression groups using randomized tables which prepared by the researcher for 0,3 and 7 minutes allocated to compare hemoglobin drop.

Participants/Inclusion and exclusion criteria

Inclusion criteria : kidney stone surgery candidate for percutaneous nephrolithotomy (PCNL), Age 18 years and older, Being in the ASA1,2 group for anesthetic risk
Exclusion criteria: Stone kidney with anatomical anomalies (malformation, pelvic kidney, horseshoe kidney), BMI more than 30, Untreated coagulation disorder, Aspirin intake in the last 7 days, Taking nonsteroidal anti-inflammatory drugs in the last 5 days, Untreated Urinary Tract Infection, Severe pulmonary disease or other conditions that, according to an anesthetist, may not be pressure on the ipsilateral abdomen

Intervention groups

Control group: Patients who eligible for percutaneous nephrolithotomy (PCNL) surgery with tubeless and at the end of operation have not any abdominal-flank compression. Intervention group: Patients who eligible for PCNL surgery with tubeless have 3 or 7 minutes flank compression at the end of operation.

Main outcome variables

Percentage of hemoglobin drop after 1 and 2 days of the after tubeless percutaneous nephrolithotomy surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043925N1**

Registration date: **2019-07-18, 1398/04/27**

Registration timing: **prospective**

Last update: **2019-07-18, 1398/04/27**

Update count: **0**

Registration date

2019-07-18, 1398/04/27

Registrant information

Name

Robab Maghsoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 8602

Email address

maghsoudi.r@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-28, 1398/05/06

Expected recruitment end date

2019-10-28, 1398/08/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemoglobin drop after tubeless percutaneous nephrolithotomy with flank compression on 0,3,7 minutes, aclinical trial

Public title

Investigation the effect of hemoglobin drop in kidney stone disease surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients who have kidney stone and are eligible for percutaneous nephrolithotomy (PCNL) surgery 18 Age and above Being in the (American Society of Anesthesiologists 1,2) ASA 1,2 group for anesthetic risk

Exclusion criteria:

Patients with stones in the kidney have anatomical anomalies (malformation, pelvic kidney, horseshoe kidney) With BMI more than 30 Untreated coagulation disorder Taking aspirin during last 7 days Taking (Nonsteroidal Anti-inflammatory Drug) NSAID drugs during last 5 days Untreated urinary tract infection Severe pulmonary disease or other conditions that, according to an anesthetist, may not be pressure on the ipsilateral abdomen.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual simple randomized and systematic: Samples were randomly assigned to two groups by using binary blocking and randomly assigned to three groups of compression for zero (as control group), three, and seven minutes using random numbered tables prepared by the researcher. A random number table is prepared by a design consultant and is provided to the researcher in closed envelopes. Once the envelope has been completed, the envelope is opened and the duration of the flank compression is determined, the same time compression of abdominal flank area is done by the surgeon or assistant. Sampling is performed from the beginning of the study successively from all eligible patients. Random instrument: sealed envelope, randomized tables prepared by the researcher, data entered into SPSS software and ANOVA test to compare the amount of bleeding.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Ethics Committee for Biomedical Research

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5th floor, Shahid Hemmat West Highway between the intersection of Sheikh Fazlollah and Shahid Chamran ,Iran University of Medical Sciences, Tehran

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Postal code

1449614535

Approval date

2019-03-16, 1397/12/25

Ethics committee reference number

IR.IUMS.FMD.REC.1397.343

Health conditions studied**1****Description of health condition studied**

Kidney stone larger than 2 centimeters

ICD-10 code

N20.2

ICD-10 code description

Calculus of kidney with calculus of ureter

2**Description of health condition studied**

Extracorporeal Shock Wave Lithotripsy (ESWL)-resistant kidney stones

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

3**Description of health condition studied**

Minor calyces stones larger than 1 centimeter and upper ureter stones larger than 1 centimeter.

ICD-10 code

N21.9

ICD-10 code description

Calculus of lower urinary tract, unspecified

4

Description of health condition studied

Cystine stones stone size with 1.5 centimeter

ICD-10 code

N21.1

ICD-10 code description

Calculus in urethra

Primary outcomes

1

Description

Access place

Timepoint

Before starting the intervention

Method of measurement

Radiography

2

Description

Kidney stone size

Timepoint

Before the intervention begins, multiply the largest diameter in the width of the stone

Method of measurement

Spiral CT abdomen and pelvis

3

Description

Experience of open kidney stone surgery

Timepoint

A day before starting the intervention

Method of measurement

Questionnaire and medical evidence

4

Description

Experience of percutaneous nephrolithotomy surgery

Timepoint

A day before starting intervention

Method of measurement

Medical evidence and questionnaire

5

Description

Diabetic

Timepoint

A day before the intervention

Method of measurement

Medical evidence

6

Description

Patient weight

Timepoint

A day before the intervention

Method of measurement

Questionnaire

7

Description

Height

Timepoint

A day before the intervention

Method of measurement

Questionnaire

8

Description

Medicine consumption

Timepoint

A day before the intervention

Method of measurement

Questionnaire

9

Description

Gender (male, female)

Timepoint

A day before the intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Duration of surgery

Timepoint

Before starting the intervention according to evaluation access for taking out the amplatz

Method of measurement

chornometer

2

Description

Creatinine

Timepoint

Measuring the creatinine a day before starting the intervention

Method of measurement

Laboratory analyzer

3

Description

Amount of creatinine

Timepoint

Measuring creatinine a day after the intervention

Method of measurement

Laboratory analyzer

4

Description

Hemoglobin

Timepoint

On the first day after the intervention in those who have abdominal flank compression .

Method of measurement

Laboratory Analyzer

5

Description

Hemoglobin

Timepoint

On the second day after the intervention in those who have abdominal flank compression .

Method of measurement

Laboratory Analyzer

6

Description

Flank's compression time

Timepoint

After starting the intervention

Method of measurement

Chronometer

7

Description

Age

Timepoint

A day before the percutaneous nephrolithotomy surgery

Method of measurement

Questionnaire

8

Description

The transfused blood

Timepoint

Before the intervention and 24 hours after the surgery

Method of measurement

3 liters blood in one third, two thirds serum in the operating room by section nurse

Intervention groups

1

Description

Control group: People who undergo kidney stone surgery through the skin due to kidney stones (the standard practice of percutaneous nephrolithotomy, PCNL) are examined. If the surgery finishes with tubeless method then the patients eligible to enter to the study and randomly assigned to three groups of compression of the flank-abdomen with the surgeon's hands for zero, three and seven minutes to control bleeding. The group which undergo the percutaneous nephrolithotomy surgery without insertion of nephrostomy tube and without any

flank-abdominal compression is considered as a control group.

Category

Treatment - Surgery

2

Description

First intervention group: The persons who have 3 minutes flank compression on abdominal area after finishing tubeless percutaneous nephrolithotomy surgery for control bleeding .

Category

Treatment - Surgery

3

Description

Second intervention group: the persons who have 7 minutes flank compression on abdominal area after finishing tubeless percutaneous nephrolithotomy surgery for control bleeding .

Category

Treatment - Surgery

4

Description

Third intervention group: the persons who have between 3 and 7 minutes flank compression on abdominal area after finishing tubeless percutaneous nephrolithotomy surgery for control bleeding .

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center**Name of recruitment center**

Hashemi nejad hospital

Full name of responsible person

Robab Maghsoudi

Street address

Vanak Sq, Valiasr St, Vali nejad Ave, Hashemi nejad hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Robab Maghsoudi

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Robab Maghsoudi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Full name of responsible person

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Position

Associate professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available