Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of hemoglobin drop after tubeless percoutaneous 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 percoutaneous 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 percoutaneous 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 percoutaneous 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 percoutaneous 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 percoutaneous 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

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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 percoutaneous 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 percoutaneous 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

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

City
Tehran

Province
Tehran

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 percoutaneous 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 percoutaneous 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 percoutaneous 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 percoutaneous 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 percoutaneous 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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Tehran
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1969714713
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Email
Maghsoudi.R@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Robab Maghsoudi

Street address
No 402,4th floor, Sina building, Vali nejad Ave, Vanak Sq, Valiasr St

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Maghsoudi.R@iums.ac.ir

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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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

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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