

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of blood loss volume in patient with Percutaneous nephrolithotripsy between spinal & general anesthesia. lithotripsy

Protocol summary

Summary

In this controlled randomized double blind clinical trial, after approval of research and ethic committee of medical faculty , for study of bleeding in spinal anesthesia versus general anesthesia in percutaneous nephrolithotripsy, 80 patient with 18-80 years old and ASA class1 whom candidate for elective percutaneous nephrolithotripsy was selected for study. patient who had significant comorbidity and sensitivity to local anesthetic drugs was excluded from study. after receiving inform consent they are divided randomly to two groups. in the group1(general anesthesia) received 5mg/kg nesdonal and maintained with 100 microgr/kg/min of propofol, in group2(spinal anesthesia)3cc bupivacain into subarachnoid space was administerd. Estimated blood loss and transfusion rate in two groups, then collected data were analyzed by SPSS16 software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101175632N1**

Registration date: **2011-09-01, 1390/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-09-01, 1390/06/10

Registrant information

Name

Gholamhosain Shirkhany

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research, tehran University of Medical Sciences

Expected recruitment start date

2010-04-04, 1389/01/15

Expected recruitment end date

2010-09-23, 1389/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of blood loss volume in patient with Percutaneous nephrolithotripsy between spinal & general anesthesia. lithotripsy

Public title

effect of general anesthesia and spinal anesthesia in percutaneous nephrolithotripsy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:age above 18 years-kidney stone with 20-40mm-American Society of Anesthesiologists score =I
exclusion ceriteria:significant comorbidity-pregnancy-severe obesity-sensitivity to local anesthetic.

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 the tehran university of medical science

Street address

Ihemmat pardis, hemmat free way, medicin faculty, research deputy

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Postal code

1969714713

Approval date

2009-08-27, 1388/06/05

Ethics committee reference number

4397

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

stone in kidney

ICD-10 code

Diseases o

ICD-10 code description

Calculus of kidney

Primary outcomes**1****Description**

blood loss volume

Timepoint

during intervention

Method of measurement

visual estimation of blood loss in the bottle as well as counting the bloody gauzes

2**Description**

need for transfusion

Timepoint

after intervention

Method of measurement

refer to patient file

Secondary outcomes**1****Description**

blood pressure

Timepoint

during procedure

Method of measurement

automatic BP monitoring

Intervention groups**1****Description**

in the spinal group 3cc bupivacain into subarachnoid space was administered.

Category

Treatment - Drugs

2**Description**

in the general anesthesia group received 5mg/kg nesdonal and maintained with 100 microgr/kg/min of propofol

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hashminezha Hospital

Full name of responsible person

Gholamreza Movasaghi MD

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Vali nezhad st, Valiasr av, Hasheminezhad Hospital

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Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

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Grant name

123455

Grant code / Reference number

099876

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

Yes

Title of funding source

Tehran 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**

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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*