

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Opioid sparing effects of intra-venous paracetamol after Percutaneous Nephrolithotomy: a randomized double blinded controlled trail

Protocol summary

Summary

1) Objectives: The aim of current study is to evaluate Pethidine-sparing effect of intravenous paracetamol and its effect on reducing pain scores after percutaneous nephrolithotomy (PCNL). 2) Design: Randomized double blind controlled trial (parallel design). 3) Setting and conduct: In Hasheminejad kidney center, our study intervention and placebo will be randomly allocated to the enrolled patients (PCNL cases) using balance blocked randomization. 4) Participants including major eligibility criteria: Enrolled patients will be randomly allocated to 100 placebo and paracetamol groups using balance blocked randomization method (50 patients in each group).inclusion criteria is, Renal calculi candidate for PCNL, Age between 18 -70 years old, American Society of Anesthesiologists (ASA) risk class I (normal healthy patient) and exclusion criteria is, pregnancy and lactation, Drug and alcohol abuse, Previous history of any allergy to acetaminophen and opioid and Bleeding tendency. 5) Intervention: In paracetamol group, each patient will receive 100cc normal saline and 1gr paracetamol intravenously 30 minutes after extubation and then every 8 hours until 24 hours. In the control group they will received 100cc of normal saline 30 minutes after extubation and every 8 hours for 24 hours (4 times overall). All patients in both groups will receive 25-50mg intramuscular pethidine, after extubation on the basis of patient demand to the maximum of 200mg/ day. 6) main out come (measures, variables): In both groups, patients pain perception will be recorded using a 100mm visual analog scale (VAS), 30 minutes, one, 4, 8, 12, 16, 20 and 24 hours after extubation. Also pain perception will be recorded on each patient's demand for rescue opioid analgesic. Ten percent loss to follow up is acceptable. Primary dependent variable is pain score, and paracetamol dose is independent variable. Pethidine dose received by each patient is considered as the secondary dependent variable.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105166504N1**

Registration date: **2011-08-08, 1390/05/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-08-08, 1390/05/17

Registrant information

Name

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Name of organization / entity

Iran University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences Vice Chancellor
For Research

Expected recruitment start date

2011-06-14, 1390/03/24

Expected recruitment end date

2011-08-14, 1390/05/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Opioid sparing effects of intra-venous paracetamol after Percutaneous Nephrolithotomy: a randomized double blinded controlled trail

Public title

Opioid sparing effects of intra-venous paracetamol after Percutaneous Nephrolithotomy: a randomized double blinded controlled trail

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Renal calculi candidate for PCNL; Age between 18 -70 years old; American Society of Anesthesiologists (ASA) risk class I (normal healthy patient)). Exclusion criteria: Pregnancy and lactation; Drug and alcohol abuse; Previous history of any allergy to acetaminophen and opioid; Previous history of hepatic (transaminase exciding two times and more of normal limits) or renal failure (serum creatinine exciding 1.5 mg/dl); Bleeding tendency; Consumption of mono-amino-oxidase inhibitors (MAO inhibitors) or their discontinue over past 2 weeks; Other painful physical conditions which might confound pain assessment; Psychiatric or medical conditions that might impair communication or compliance with the study procedures; Use of NSAIDs or other analgesic drug within 12 h preceding study medications; Age below 18 and above 70 years old

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of medical science, Ethics committee

Street address

Tehran University of Medical Scince, Hemat high way, Paradise Hemat.

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Tehran

Postal code

Approval date

2011-05-22, 1390/03/01

Ethics committee reference number

130/1263

Health conditions studied

1

Description of health condition studied

PCNL

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

Pain score

Timepoint

every 4 hours

Method of measurement

VAS

2

Description

paracetamol dose

Timepoint

every 8 hours

Method of measurement

patient records

Secondary outcomes

1

Description

Pethidine dose

Timepoint

After PCNL surgery

Method of measurement

Patients' records

Intervention groups

1

Description

Enrolled patients will be randomly allocated to 100 placebo and paracetamol groups using balance blocked randomization method (50 patients in each group). In

paracetamol group, each patient will receive 100cc normal saline and 1gr paracetamol intravenously 30 minutes after extubation and then every 8 hours until 24 hours.

Category

Treatment - Drugs

2**Description**

In control group: In the control group they will received 100cc of normal saline 30 minutes after extubation and every 8 hours for 24 hours (4 times overall).

Category

Treatment - Drugs

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

Hasheminejhad Hospital

Full name of responsible person

Saeed Haghdani

Street address

Valinejad Ave, Vanak Sq, Valiasr St

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Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences-Vice Chancellor for Research

Full name of responsible person

Dr Akbar Fotouhi

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No. 21, Damascus St., Palestine St., Keshavarz Blvd. Vali-e-Asr Ave.,

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Tehran

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-Vice Chancellor for Research

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