Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Hasheminejhad 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

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Name of organization / entity
Iran University of Medical sciences
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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, Pardise Hemat.

City
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

City

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

Street address

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

City

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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Other areas of specialty/work

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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