

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of intravenous acetaminophen in comparison with pethidine for pain relief in renal colic

Protocol summary

Summary

Renal colic or acute flank pain is caused by the passage of urinary tract stones. The most important task in emergency room is to control this pain. Therefore, the aim of this study is to investigate the effect of intravenous acetaminophen to control pain in comparison with pethidine in patients with renal colic who had been referred to the emergency department. This study in a randomized clinical trial and single blind in which a sample of 100 patients with colic pain, aged between 18 to 60 years were used. Patients were randomly divided into two control and interventions groups. The control group was received pethidine and the intervention group is infused with acetaminophen. After the injection pain was assessed using visual analogue scale immediately after intervention, and 5, 10, 20 and 30 minutes following intervention. t-test and chi-square were used for analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090429690N1**
Registration date: **2016-10-14, 1395/07/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-14, 1395/07/23

Registrant information

Name

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Name of organization / entity

Ardabil university Medical of Sciences

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Recruitment status

Recruitment complete

Funding source

Ardabil university of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous acetaminophen in comparison with pethidine for pain relief in renal colic

Public title

Comparison of intravenous acetaminophen and pethidine in pain renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 to 60 years old; pain score less than 8. Exclusion criteria: pregnant women; breast feeding; have used painkillers in 6 hours before; renal dysfunction; warfarin therapy; using opioids; bleeding disorders; people who are addicted to drugs.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 100

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 Ardabil University of Medical Sciences

Street address

End of University Avenue. Headquarters of Ardsbil University of medical sciences

City

Ardabil

Postal code

Approval date

2016-04-08, 1395/01/20

Ethics committee reference number

IR.ARUMS.REC.1395.46

Health conditions studied

1

Description of health condition studied

Renal Colic

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

Pain

Timepoint

Before intervention, 5, 10, 20 and 30 minuts after intervention

Method of measurement

Visual Analogous Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : intravenous acetaminophen dose intravenous injections of acetaminophen 1 g in 100 ml of sodium chloride solution and the mixture was injected.

Category

Treatment - Drugs

2

Description

contorol group: 50 mg of pethedine intramuscularly was used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil Fatemi Hospital

Full name of responsible person

Jafar Ghobadi

Street address

Fatemi hospital

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ardabil University of Medical Sciences

Full name of responsible person

Shahram Habibzadeh

Street address

Deputy of research and technology . the headquarters of the Medical university of Ardabil .End of University Avenue . Ardabil

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Ardabil University of Medical

Sciences
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