

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The comparison of Apotel (intravenous acetaminophen) with intravenous morphine in patients with acute renal colic

Protocol summary

Summary

Study objective: To evaluate the clinical efficacy of intravenous acetaminophen in lowering the dose of morphine in renal colic in Imam Reza (AS) Educational-Therapeutic Center of Tabriz University of Medical Sciences; Design of study: randomized, single blind, not-placebo controlled, single center trial; Inclusion criteria: patients 18-50 years old; known case of kidney stone. Exclusion criteria: using any drug for pain prior to attendance; allergy to the administered medications; history of opioid dependence; hypertension; fever and chills ; pregnancy and pain intolerance during the first 35 min of drug administration; Sample size: 100 divided in Two Groups Including intravenous 1 gram acetaminophen with Low Dose Morphine in Intervention Group vs. Intravenous 1mg/kg of morphine in control group; Duration of Intervention: 35 minutes; The effect of two drugs is evaluated based on pain intensity VAS system in minutes 0, 1, 5, 10, 15, 25 and 35 after Administration.

General information

Acronym

rss

IRCT registration information

IRCT registration number: **IRCT2013071411555N1**

Registration date: **2014-05-17, 1393/02/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-17, 1393/02/27

Registrant information

Name

Hamidreza Mortezaeigi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of Apotel (intravenous acetaminophen) with intravenous morphine in patients with acute renal colic

Public title

Evaluation of the effect of intravenous acetaminophen in lowering the dose of morphine in renal colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients 18-50 years old; known case of kidney stone. Exclusion criteria: using any drug for pain prior to attendance; allergy to the administered medications; history of opioid dependence; hypertension; fever and chills ; pregnancy and pain intolerance during the first 35 min of drug administration; pain intolerance

during the first 35 min of drug administration.

Age

From **18 years** old to **50 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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University, Medical Sciences Building

City

Tabriz

Postal code

Approval date

2013-06-12, 1392/03/22

Ethics committee reference number

9243

Health conditions studied

1

Description of health condition studied

renal colic

ICD-10 code

n20,n21,n2

ICD-10 code description

Calculus of kidney and ureter which can cause colicky pain

Primary outcomes

1

Description

pain severity

Timepoint

0, 1, 5, 10, 15, 25 and 35 min after drug administered

Method of measurement

visual analogue scale

Secondary outcomes

1

Description

probable complications

Timepoint

during procedure until 1 week after discharge

Method of measurement

according to history and physical examination

Intervention groups

1

Description

In intervention group, which the sample will be selected randomly out of 100 patients admitted with acute renal colic, 1 gram of Intravenous Acetaminophen (Aptel) combined with a low dose of Morphine will be administered.

Category

Treatment - Drugs

2

Description

In Control group, which will be selected randomly from the population of 100 patients admitted with acute renal colic, morphine will be administered intravenously with the dose of 0.1 mg/kg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency Department of Imam Reza (AS) Educational-Therapeutic Centre

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Hamidreza Morteza Beigi

Street address

Emergency department of Imam Reza (AS)
Educational-Therapeutic Centre

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Hamidreza Morteza Beigi

Position

Specialty-assitant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Position

Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

Web page address

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