

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the efficacy of intravenous paracetamol versus intravenous morphine plus diclofenac in treatment of renal colic

Protocol summary

Summary

Title: Comparison of the efficacy of intravenous paracetamol versus intravenous morphine plus diclofenac in treatment of renal colic Purposes: Determination the severity of the pain on the basis of Visual Analogue Scale before treatment, 10 and 20 and 30 minutes and 24 hours after treatment. Determination the time required for analgesia in apotel group and diclofenac plus morphine group. Design, method and interventions: Among the all patients, 180 patients will be selected randomly.sample will be divided in two groups. In the first group after the diagnosis, 1 gram intravenous acetaminophen will be solved in 100 cc normal saline and will be infused in 10 minutes. In the second group 0.1 milligram morphine with 75 milligram diclofenac will be solved in 100 cc normal saline and will be infused in 10 minutes. Inclusion criteria: Documented renal stone on the basis of CT scan or KUB Exclusion criteria: Patients with NSAIDs contraindication; patients who have received opioid in the last 6 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405127327N3**

Registration date: **2015-02-01, 1393/11/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-01, 1393/11/12

Registrant information

Name

Samad Shams Vahdati

Name of organization / entity

Tabriz University of Medical Scinces

Country

Iran (Islamic Republic of)

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+98 41 1658 1401

Email address

shams@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-06-05, 1393/03/15

Expected recruitment end date

2014-12-06, 1393/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of intravenous paracetamol versus intravenous morphine plus diclofenac in treatment of renal colic

Public title

Comparison of the efficacy of paracetamol versus intravenous morphine plus diclofenac in decreasing the pain of renal stones

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Documented renal stone on the basis of CT scan or KUB Exclusion criteria: Patients with NSAIDs contraindication; patients who have received opioid in the last 6 hours.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample sizeTarget sample size: **180****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**

Local Ethics Committee, Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Gholghasht Street, Daneshgah Street, Tabriz

City

Tabriz

Postal code**Approval date**

2014-02-24, 1392/12/05

Ethics committee reference number

5/4/10986

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

Pain due to renal stone

ICD-10 code

N23

ICD-10 code description

Unspecified renal colic

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

Pain severity

Timepoint

In intrance, 10min, 20min, 30 min and 24 hour after treatment

Method of measurement

Visual analogue Scale

Secondary outcomes

empty

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

Intervention group: After diagnosis, 1 gram intravenous acetaminophen will be solved in 100 cc normal saline and will be infused in 10 minutes. Drug name: Apotel
 Drug compound: Acetaminophen Dose: one gram intravenous acetaminophen in 100 cc normal saline

Category

Treatment - Drugs

2**Description**

Control group: 0.1 milligram morphine and 75 milligram diclofenac will be solved in 100 cc normal saline and will be infused in 10 minutes. Drugs name: Morphine and Diclofenac Dose: 0.1 milligram morphine and 75 milligram diclofenac in 100 cc normal saline

Category

Treatment - Drugs

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

The Emergency Department of Imam Reza Hospital

Full name of responsible person**Street address****City**

Tabriz

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

Student Research committee, Tabriz university of Medical Sciences

Full name of responsible person

Dr. Somaieh Halaj Nezhadi

Street address

Education development center, Daneshgah street, Tabriz

City

Tabriz

Grant name**Grant code / Reference number**

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

Yes

Title of funding source

Student Research committee, 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. Samad Shams Vahdati

Position

Assistant Professor of emergency medicine

Other areas of specialty/work

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Name of organization / entity

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Full name of responsible person

Dr. Samad Shams Vahdati

Position

Assistant Professor of Emergency Medicine

Other areas of specialty/work

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City

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Postal code

Phone

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Fax

Email

shams@tbzmed.ac.ir; sshamsv@yahoo.com

Web page address

Person responsible for updating data

Contact

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