Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Samad Shams Vahdati
Name of organization / entity
Tabriz University of Medical Scinces
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Iran (Islamic Republic of)
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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 size
Target 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 Siences, 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
Tabirz

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, Daneshghah 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
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Position
Assistant Professor of emergency medicine
Other areas of specialty/work
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Postal code
Phone
+98 41 1335 2078
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