

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

A clinical trial comparing the effects of apotel to normal saline on pain relief, need for narcotics, and side effects among renal colic patients

Protocol summary

Summary

Objective: Evaluation of the effects of apotel and normal saline on pain relief, need for narcotics, and side effects among renal colic patients. Design: A double-blind, block randomized clinical trial. Study population: Renal colic patients. Inclusion criteria: Renal colic patients; having weight between 50 and 80 kg; aged between 18 and 50 years. Exclusion criteria: History of allergy to narcotics or acetaminophen; chills and fever; urinary tract infection based on laboratory findings; history of drug abuse, receiving narcotics or other analgesics during six hours before admission; pregnancy; history of renal, cardiac, respiratory, or hepatic failure; history of renal transplantation; abdominal aortic aneurysm; history of hypertension or hemodynamic instability. Sample size: 110 cases. Study intervention: The control group will receive 1 g of IV normal saline with 0.05 mg/kg of IM morphine. The intervention group will receive 1 g of IV apotel with 0.05 mg/kg of IM morphine. Study outcome: Evaluation and comparison of pain level pre- and 30 minutes post-intervention based on Visual Analogue Scale (VAS) and investigation of side-effects of the administered agents based on a questionnaire in the intervention and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051425507N3**

Registration date: **2016-05-25, 1395/03/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-25, 1395/03/05

Registrant information

Name

Ali Serous

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Arak University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing the effects of apotel to normal saline on pain relief, need for narcotics, and side effects among renal colic patients

Public title

Effectiveness of apotel injection in renal colic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Renal colic patients; having a weight between 50 and 80 kg; aged between 18 and 50 years. Exclusion criteria: History of allergy to narcotics or

acetaminophen; chills and fever; urinary tract infection based on laboratory findings; history of drug abuse, receiving narcotics or other analgesics during six hours before admission; pregnancy; history of renal, cardiac, respiratory, or hepatic failure, history of renal transplantation; abdominal aortic aneurysm; history of hypertension or hemodynamic instability.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

randomization using blocks

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Vice Chancellor for Research, Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street

City

Arak

Postal code

Approval date

2015-05-07, 1394/02/17

Ethics committee reference number

IR.ARAKMU.REC.1394.321

Health conditions studied

1

Description of health condition studied

Renal colic

ICD-10 code

N23.0

ICD-10 code description

Unspecified renal colic

Primary outcomes

1

Description

Pain level

Timepoint

Pre- and 30 minutes post-intervention

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Side-effects of pharmaceuticals, include nausea, vomiting, hypotension, itching and drowsiness.

Timepoint

Half an hour after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Control group: Renal colic patients will receive 1 g of IV normal saline with 0.05 mg/kg of IM morphine, and their level of pain will be assessed pre- and 30 minutes post-intervention based on Visual Analogue Scale (VAS).

Category

Treatment - Drugs

2

Description

Intervention group: Renal colic patients will receive 1 g of IV apotel (acetaminophen injection made of COMBINO PHARM company) with 0.05 mg/kg of IM morphine, and their level of pain will be assessed pre- and 30 minutes post-intervention based on Visual Analogue Scale (VAS).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Ali Sirous

Street address

Valiasr Hospital- Pyrozi Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Arak University of Medical Sciences

Full name of responsible person

Ali Asghar Yaghobi

Street address

Vice Chancellor for Research, Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street Arak

City

Arak

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 of Arak 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

Arak University of Medical Sciences

Full name of responsible person

Ali Sirous

Position

Urologist

Other areas of specialty/work

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Other areas of specialty/work

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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