Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Nov 2026

Comparison of the effect ofmorphine and oxycodone onacute renal colic

Protocol summary

Study aim
Comparison of the effect ofmorphine and oxycodone onacute renal colic
Design
This double-blind and clinical trial .54 patients with renal colic at Valiasr Hospital in Arak. We will divide patients in 2 groups by simple randomization. Groups are parallel.
Settings and conduct
This double-blind and clinical trial .54 patients with renal colic at Valiasr Hospital in Arak. We will divide patients in 2 groups by simple randomization with envelopes.The study is double-blind.Outcome elevator and analyzer and participant are blind (double blind).
Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 60, no drug addiction, pain caused by renal colic, people who have less than 8 pain criteria, not receiving housing in the last 6 hours, people whose pain does not decrease after 2 hours Exclusion criteria:Vomiting after taking oral painkillers, conscious dissatisfaction
Intervention groups
In the placebo group, 27 patients receive morphine in the amount of 5 milligram of oral placebo and in the second group, 27 patients received 10 milligram of oxycodone and injectable placebo.
Main outcome variables
Pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200702047986N1**
Registration date: **2020-09-05, 1399/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-05, 1399/06/15**
Update count: **0**
Registration date
2020-09-05, 1399/06/15

Registrant information
Name
Davoud Shabani
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-06-21, 1399/04/01
Expected recruitment end date
2021-06-22, 1400/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect ofmorphine and oxycodone onacute renal colic

Public title
Comparison of the effect ofmorphine and oxycodone onacute renal colic
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 60 No drug addiction Pain caused by renal colic People who have less than 8 pain criteria Not receiving housing in the last 6 hours People whose pain does not decrease after 2 hours

Exclusion criteria:
Vomiting after taking oral painkillers Conscious dissatisfaction

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with randomization with envelopes in 2 groups A and B. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is clinical trial.Outcome elevator and analyzer and participant are blind (double blind).Outcome elevator and analyzer and participant don't aware from group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of Arak University Of Medical Sciences

Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2020-06-14, 1399/03/25

Ethics committee reference number
IR.ARAKMU.REC.1399.096

Health conditions studied

1

Description of health condition studied
Renal colic

ICD-10 code
N23

ICD-10 code description
Unspecified renal colic

Primary outcomes

1

Description
Pain

Timepoint
At zero hours (before prescribing the drug) and 30 minutes and two hours after receiving the drug

Method of measurement
Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Twenty-seven patients received 10 mg of oxycodone from the University Narcotics Office in the form of two 5 mg oral tablets at the same time and an intravenous injection placebo only once at the time of admission.

Category
Treatment - Drugs

2

Description
Control group: In the second group, 27 patients received injectable morphine sulfate from the University Narcotics Office, 5 mg intravenously as a single placebo and placebo oral tablets only once at the beginning of hospitalization.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr hospital

Full name of responsible person
Dr Mohammad Jamalian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Arak University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr Mohammad Jamalian

Position
Assistant

Latest degree
Specialist

Other areas of specialty/work
Forensic Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person
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General Practitioner
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available