Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

The effect of adding sublingual desmopressin to the intravenous treatment with Apotel and ketorolac in patients with mild to moderate renal colic pain

Protocol summary

Study aim

Determining the effect of adding sublingual desmopressin to intravenous treatment with Apotel and ketorolac in patients with mild to moderate renal colic pain. Using the results and information of this study to measure the effectiveness of desmopressin in controlling the pain of renal colic and reducing the amount of pain while having fewer and cheaper side effects is the availability of desmopressin.

Design

A controlled, parallel-group, unblinded, randomized, phase 3 clinical trial on 102 randomized sealed envelopes.

Settings and conduct

Clinical trial on the effect of desmopressin in renal colic, emergency department of Imam Khomeini hospital in Ahvaz and emergency department of Golestan hospital in Ahvaz, patients who have renal colic and meet the inclusion criteria are randomly selected into two intervention and control groups, and desmopressin intervention group It will be given

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with renal colic who have not received painkillers in the last three hours and are not suffering from high blood pressure, coronary artery disease, gastric ulcer, kidney failure and liver failure and are not taking anticoagulant treatment and are not pregnant.

Intervention groups

In group A (control), apotel 1g and ketorolac 30mg are injected, and group B (intervention) apotel 1g and ketorolac 30mg are injected, and a sublingual tablet of desmopressin is placed under the patient's tongue.

Main outcome variables

Determining the amount of pain in control and intervention group at times zero, 15m , 30m , 45 m ,60m and comparing them comparison of pain reduction time in intervention and control group comparison the speed of pain reduction in intervention and control group Determining of complications in control and intervention group and comparing them

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230704058673N1**
Registration date: **2023-08-19, 1402/05/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-19, 1402/05/28**
Update count: **0**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

mojtaba sasani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3392 4155

Email address

sasani-m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-21, 1402/04/30

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding sublingual desmopressin to the intravenous treatment with Apotel and ketorolac in patients with mild to moderate renal colic pain

Public title

The effect of desmopressin in reducing the pain of renal colic patientsSearch for this on Google

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with renal colic who have not received painkillers in the last three hours Do not have hypertension Do not have coronary artery disease Do not have gastric ulcers Do not have renal failure Do not have liver failure Do not pregnant Do not take anticoagulants

Exclusion criteria:

Patients who become unstable in terms of vital signs Have changes in blood pressure Tachycardia Headache dizziness seizure Occurrence of drug side effects Intolerance of pain during the study

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients are randomly assigned between groups A and B in a 1:1 ratio using sealed envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in the research of Golestan Hospital

Street address

Goletan . farvardin bolvar . goletan hospital . emergency department

City

ahvaz

Province

Khouzestan

Postal code

6135733118

Approval date

2023-05-20, 1402/02/30

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1402.053

Health conditions studied

1

Description of health condition studied

The effect of adding sublingual desmopressin to the intravenous treatment with Apotel and ketorolac in patients with mild to moderate renal colic pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

intensity of pain

Timepoint

zero, 15 minutes, 30 minutes, 45 minutes, 60 minutes,

Method of measurement

Using the visual analog scale (VAS) for this purpose, the printed VAS ruler is shown to the patients and they are asked to indicate the number that represents their current pain.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Mojtaba Sasani
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Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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
Ahvaz 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
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Person responsible for updating data

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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
Not applicable

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