

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 patients
Search 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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2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Ahvaz

Full name of responsible person

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Twenty-four meter street. Imam Khomeini Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi moghaddam

Street address

Golestan Ave,Jondishapur university

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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

Ahvaz University of Medical Sciences

Full name of responsible person

Mojtaba Sasani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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مجتبی ساسانی

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Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mojtaba Sasani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Phone**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