Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of inhaled Desmopressin and Pethidine in combination with Diclofenac in relieving pain caused by renal colic

Protocol summary

Study aim
Determining and comparing the effects of inhaled desmopressin with diclofenac suppository and pethidine ampoules with diclofenac suppository in relieving pain caused by renal colic

Design
Clinical trial, with parallel groups, phase 3 on 80 patien

Settings and conduct
A study comparing the palliative effects of two drugs in Sabalan Hospital in Ardabil will be a clinical trial. Patients will be divided into two intervention groups A and B. Group A is patients receiving inhaled desmopressin and diclofenac suppository and group B is patients receiving pethidine and diclofenac. Visual Analog Scale (VAS) pain will be measured at 15 and 30 minutes upon arrival at the emergency room.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with renal colic. Exclusion criterias: active gastrointestinal ulcer, renal failure, hypothyroidism, systolic blood pressure less than 80, asthma, emphysema, benign prostatic hyperplasia

Intervention groups
80 patients who will refer to Sabalan Hospital in Ardabil with symptoms of renal colic will be included in the study. Patients will divided into two groups A and B. Group A will be given 40 micrograms of inhaled desmopressin plus 100 mg of diclofenac suppository and group B 50 mg of intravenous pethidine plus 100 mg of diclofenac suppository

Main outcome variables
Renal colic based on VAS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201214049708N1**
Registration date: **2020-12-31, 1399/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-31, 1399/10/11**
Update count: **0**

Registration date
2020-12-31, 1399/10/11

Registrant information
Name
Hamid Moslemi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 45 3359 2603
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hamidmoslemi1782@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-08, 1399/09/18

Expected recruitment end date
2021-02-08, 1399/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of inhaled Desmopressin and Pethidine in combination with Diclofenac in relieving pain caused by renal colic

Public title
comparison of pain relief power of desmopressin and pethidine in combination with diclofenac

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with renal colic
Exclusion criteria:
Active gastrointestinal ulcer Renal Failure Hypothyroidism Systolic blood pressure under than 80 mmgh Asthma Emphysema BPH
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Not randomized
Randomization description
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 of Azad University of Tabriz Province
Street address
Basij Square - Azad University - School of Medicine
City
Ardabil
Province
Ardabil
Postal code
5615731567
Approval date
2020-12-08, 1399/09/18
Ethics committee reference number
IR.IAU.TABRIZ.REC.1399.142

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
The amount of pain caused by renal colic is measured by VAS (questionnaire)
Timepoint
Asking the amount of pain and recording it in the questionnaire at the time before the intervention, 15 minutes and 30 minutes after the intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: It is called group A. In this group, 40 people will be given 40 micrograms of inhaled desmopressin (manufactured by Sina Daru company called Desmex) in the form of a four-puff spray into the nose, plus a diclofenac suppository (manufactured by Najo company) at a dose of 100 mg single dose. Before prescribing the drug, the patient's consent is obtained and the patient is taught how to use the spray, and then the patient's pain is graded by the VAS method, and after the drug, the patient's pain is re-evaluated at 15 and 30 minutes.
Category
Treatment - Drugs

2

Description
Intervention group B: In this group, 40 people will be given 50 mg of intravenous pethidine (produced by Caspiantamin Company) which is an overnight drug, plus a diclofenac suppository (produced by Najo company) with a single dose of 100 mg. Before prescribing, education is given about the side effects of narcotics and consent is given for the injection. In this group, pain is measured at the beginning of the visit and 15 and 30 minutes later by VAS method.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sabalan Ardabil Hospital

Full name of responsible person
Hamid Moslemi

Street address
Basij Square - Ardabil Branch of Azad University - Faculty of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The Islamic Azad University of Ardabil

Full name of responsible person
Hamid Moslemi

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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
The Islamic Azad University of Ardabil

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
The Islamic Azad University of Ardabil

Full name of responsible person
Hanid Moslemi

Position
medical student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Basij Square - Islamic Azad University, Ardabil Branch - School of Medicine

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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
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