

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### 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

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

Update count: **0**

#### Registration date

2020-12-31, 1399/10/11

#### Design

Clinical trial, with parallel groups, phase 3 on 80 patient

#### Registrant information

##### Name

Hamid Moslemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3359 2603

##### Email address

hamidmoslemi1782@gmail.com

#### 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.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

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

#### 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

#### 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 be 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

#### Scientific title

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

#### Main outcome variables

Renal colic based on VAS

#### Public title

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

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201214049708N1**

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

## 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 Caspianamin 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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**Postal code**

5615731567

**Phone**

+98 45 3372 7799

**Email**

azadu119@hotmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

The Islamic Azad University of Ardabil

**Full name of responsible person**

Hamid Moslemi

**Street address**

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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

**Street address**

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## Person responsible for scientific inquiries

### Contact

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**Latest degree**

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## Person responsible for updating data

### Contact

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The Islamic Azad University of Ardabil

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**Position**

medical student

**Latest degree**

Bachelor

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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