# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Oct 2026

## A comparison of the effect of morphine and tamsulosin with morphine alone in pain management of renal colic patients

## Protocol summary


**Summary**

The purpose of the present study is to investigate the painkilling effect of morphine plus placebo in comparison with morphine plus tamsulosin. To do this research, we are going to carry out a randomized, double-blind study over 200 patients aged 18 to 55 presenting with acute renal colic to the emergency department of Imam Reza Hospital. Patients with one of the following criteria will be excluded from the study: opium addiction, pregnancy, any history of renal or hepatic disease and bilateral renal stones. After making sure that all of the inclusion criteria exist, the information about medicines' advantages and side effects are provided to the participants and a written consent is obtained from the patients in case they agree to participate in the study. Then, the patients will be divided into two groups of A and B at a random selection without the researcher's interference (based on the randomized block method using 200 Sequencing provided by statistics expert). Before the administration of the chosen drug, the patients are asked to determine their pain level based on the visual analogue scale (VAS) using the ruler of VAS which is given to them. Group A patients will be treated with 0.1 mg/kg IV morphine plus 0.4 mg of oral tamsulosin produced by Tasnim pharmaceutical company and Group B patients will be treated with the same dose of IV morphine plus placebo (empty tablet shells provided by Tasnim pharmaceutical Co., having the same shape as tamsulosin tablets, filled with starch). After 30 minutes, 2, 4 and 6 hours of the drug administration, the patients' pain level will be evaluated again based on VAS using the ruler of VAS that has been given to the patients. Finally, data collected from the two groups will be compared and analyzed.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016101311956N9**

Registration date: **2017-03-11, 1395/12/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

**Registration date**

2017-03-11, 1395/12/21

**Registrant information**

**Name**

Morteza Talebi Doluee

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 3852 5312

**Email address**

talebidm@mums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Mashhad University of Medical Sciences

**Expected recruitment start date**

2016-10-21, 1395/07/30

**Expected recruitment end date**

2017-03-19, 1395/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparison of the effect of morphine and tamsulosin with morphine alone in pain management of renal colic patients

**Public title**

A comparison of the effect of morphine and tamsulosin with morphine alone in pain management of patients with renal stone

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
Inclusion criteria: patients with renal colic; age between 18 to 55 years old. exclusion criteria: any history of opium addiction; pregnancy; any history of renal or hepatic disease; bilateral renal stones

**Age**
From **18 years** old to **55 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **200**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Mashhad University of Medical Sciences

**Street address**
Ethics Committee, Ghoreishi building, Daneshgah ave.

**City**
Mashhad

**Postal code**

**Approval date**
2016-09-11, 1395/06/21

**Ethics committee reference number**
IR.mums.fm.REC.1395.127

## 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**
Before analgesic administration and 30 minutes , 2 , 4 and 6 hours after analgesic administration

**Method of measurement**
Visual analoge scale

## Secondary outcomes

### 1

**Description**
headache

**Timepoint**
30 minutes , 2 , 4 and 6 hours after analgesic administration

**Method of measurement**
Questionnaire

### 2

**Description**
dizziness

**Timepoint**
30 minutes , 2 , 4 and 6 hours after analgesic administration

**Method of measurement**
questionnaire

## Intervention groups

### 1

**Description**
We administer morphine sulfate 0.1 mg/kg IV with oral tamsulosin 0.4 mg for the first group of patients.

**Category**
Treatment - Drugs

### 2

**Description**
We administer morphine sulfate 0.1 mg/kg IV with placebo for the second group of patients.

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Imam Reza hospital,Edalatian emergency center

**Full name of responsible person**
Dr Morteza Talebi, Emergency Medicine specialist

**Street address**
Imam Reza sq , Ebnesina ave.

**City**
Mashhad

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice Chancellor for Research, Mashhad University of Medical Sciences

**Full name of responsible person**
Dr. Mohsen Tafaghodi

**Street address**
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

**City**
Mashhad

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Vice Chancellor for Research, Mashhad University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
*empty*

**Domestic or foreign origin**
*empty*

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Mashhad University of Medical Siences

**Full name of responsible person**
Dr. Aida Shams Hojati

**Position**
MD, Resident of Emergency Medicine

**Other areas of specialty/work**

**Street address**
Department of emergency medicine , Imam Reza hospital

**City**
Mashhad

**Postal code**

**Phone**
+98 51 3762 3320

**Fax**

**Email**
shamsa931@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Department of Emergency Medicine , Mashhad University of Medical Siences

**Full name of responsible person**
Dr. Morteza Talebi

**Position**
Emergency medicine specialist , assistant professor of emergency medicine

**Other areas of specialty/work**

**Street address**
Imam Reza Hospital, Imam Reza Square, Ebne Sina Avenue

**City**
Mashhad

**Postal code**

**Phone**
+98 51 3852 5312

**Fax**

**Email**
talebimd@mums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Mashhad University of Medical Siences

**Full name of responsible person**
Dr. Aida Shams Hojati

**Position**
MD, Resident of Emergency Medicine

**Other areas of specialty/work**

**Street address**
Imam Reza Hospital, Imam Reza Square, Ebne Sina Avenue

**City**
Mashhad

**Postal code**

**Phone**
+98 51 3762 3320

**Fax**

**Email**
shamsa931@mums.ac.ir

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*

**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*