

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Analgesic Effects of Inhalation of Entonox and Parental Morphine Sulfate in Patients with Renal Colic; A Randomized Clinical Trial

Protocol summary

Summary

The aim of the current study is to compare the efficacy of inhalational Entonox and parental Morphine sulfate in patients with renal colic. We would include a total number of 100 patients with ultrasonography and CT-Scan confirmed nephrolithiasis leading to renal colic referring to our center. Those with morphin and Entonox sensitivity, those with chronic respiratory disease and those with ischemic heart diseases would be excluded. Patients would be randomly assigned to receive morphin injection (0.1 mg/kg) along with diclofenac suppository (100 mg) (n=50), or Entonox inhalation (containing 50% nitrous oxide, self-administration, in 30 minutes with mask) along with diclofenac suppository (100 mg). The pain severity would be measured at 3, 5, 10, 30 and 120 minutes after the operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120215620N4**

Registration date: **2015-05-11, 1394/02/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-11, 1394/02/21

Registrant information

Name

Alireza Majidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4407 2074

Email address

pezeshkmajidy@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Shahid Beheshti UNiversity of Medical Sciences

Expected recruitment start date

2012-12-29, 1391/10/09

Expected recruitment end date

2015-04-05, 1394/01/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analgesic Effects of Inhalation of Entonox and Parental Morphine Sulfate in Patients with Renal Colic; A Randomized Clinical Trial

Public title

Effects of Inhalation of Entonox and Parental Morphine Sulfate in Patients with Renal Colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 20-50 years; acute renal colic conformed by both ultrasonography and abdominopelvic CT-Scan Exclusion criteria: Pregnancy; asthma; chronic pulmonary obstructive disease (COPD); intestinal obstruction; hypertension; congestive heart failure; a history of surgery on kidneys and the urinary tract; peptic ulcers and gastrointestinal hemorrhage; allergy to aspirin, NSAIDs and morphine; decreased level of consciousness, head and thoracic trauma; pneumocephalus; pneumothorax (or entrapment of air in any part of the body); drug abuse; tenderness and

rebound tenderness, abdominal guarding; delayed menstruation; use of any analgesic during the previous 24 hours and at entry into the emergency ward

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Aarabi Avenue, Chamran Avenue

City

Tehran

Postal code

Approval date

2012-12-28, 1391/10/08

Ethics committee reference number

311

Health conditions studied

1

Description of health condition studied

Renal Colic

ICD-10 code

N20

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

Pain intensity

Timepoint

3, 5, 10, 30, 120 minutes after intervention

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

Drug side effects

Timepoint

3, 5, 10, 30, 120 minutes after intervention

Method of measurement

Examination

Intervention groups

1

Description

Group 1: Parenteral morphine sulfate (0.1 mg/Kg) + 100 mg Diclofenac (suppository)

Category

Treatment - Drugs

2

Description

Group 2: 30 minutes of mask ventilation with Entonox (50% nitric oxide) + 100 mg Diclofenac (suppository)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein

Full name of responsible person

Zein Alabedin Chaboksavar

Street address

Shahid Madani Street

City

Tehran

2

Recruitment center

Name of recruitment center

Shohadaye Tajrish

Full name of responsible person

Alireza Majidi

Street address

Tajrish Square

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research, Shahid Beheshti Medical University

Full name of responsible person

Afshin Zarghi

Street address

Shahid Aarabi street, Shahid Chamran Avenue

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor of Research, Shahid Beheshti Medical University

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**

Shahid Beheshti Medical University

Full name of responsible person

Zein Alabedin Chaboksavar

Position

Emergency Medicine Residency

Other areas of specialty/work**Street address**

Shahid Aarabi Street, Shahid Chamran Avenue

City

Tehran

Postal code**Phone**

+98 21 2240 0207

Fax**Email**

Zchaboksavar@yahoo.com

Web page address

Person responsible for scientific

inquiries

Contact**Name of organization / entity**

Shahid Beheshti Medical University

Full name of responsible person

Majidi Alireza

Position

Assistant Professor

Other areas of specialty/work**Street address**

Shohadaye Tajrish Hospital, Tajrish Square

City

Tehran

Postal code**Phone**

+98 21 2271 8000

Fax**Email**

Pezeshkmajidy@sbmu.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Shahid Beheshti Medical University

Full name of responsible person

Zein Alabedin Chaboksavar

Position

Emergency Medical University

Other areas of specialty/work**Street address**

Shahid Aarabi, Shahid Chamran Avenue

City

Tehran

Postal code**Phone**

00

Fax**Email**

Zchaboksavar@yahoo.com

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