

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of Nitrous Oxide in comparison to Oxygen combined with Fentanyl on the staying time and pain reduction in renal colic patients at Emergency room

#### Protocol summary

##### Summary

The aim of this study is to compare fentanyl+Entonox (nitrous oxide+O<sub>2</sub>) vs. fentanyl+oxygen, as analgesics agents, in patients with acute renal colic. This study is a randomized, double blinded, without placebo control and in phase 2 of clinical trial. 120 adult patients with acute renal colic, age above 18 and with stable hemodynamic presenting to emergency department will enroll. Patients were excluded if they have a drug reaction. At the beginning 50 µg fentanyl will be infused for all of the patients. After that, patients divide into two groups. The first group will receive a mask of Entonox and the second group will receive a mask of oxygen. Quantitative measurement of pain will be performed by visual analogue scale (VAS), before and 3-, 5-, 10- and 30-minute after the intervention. If the pain was not relieved after 30 minutes, 50 µg fentanyl will be infused & severity of pain will be measured again. If the pain continued, Ketorolac and Ketamine will be used. Hospitalization duration and severity of pain at specified time will be compared between patients in two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013020512369N1**

Registration date: **2016-06-19, 1395/03/30**

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

Last update:

Update count: **0**

##### Registration date

2016-06-19, 1395/03/30

##### Registrant information

###### Name

Omid Ahmadi

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3261 3464

##### Email address

o\_ahmadi@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### 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

The effect of Nitrous Oxide in comparison to Oxygen combined with Fentanyl on the staying time and pain reduction in renal colic patients at Emergency room

##### Public title

The effect of Nitrous Oxide in comparison to Oxygen combined with Fentanyl on the staying time and pain reduction in renal colic patients at Emergency room

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria were as follows: Age > 18 yr; Definite diagnosis of renal colic; Stable hemodynamic

(PR=60-100, SBP>100, SPO2>90%.RR=8-22); lack of analgesics usage during last 24 hour; absence of these conditions in patients history: asthma, COPD, intestinal obstruction, hypertension, heart failure, history of previous surgery on kidney and urinary tract, peptic ulcer, GI bleeding, previous history of allergy to fentanyl or other analgesic agents, loss of consciousness, head or chest trauma, pneumocephalus, pneumothorax, drug abuse, abdominal tenderness, rebound tenderness or guarding, retard menstruation; Fill the Informed consent form Patients were excluded if: The patient hemodynamic becomes unstable during the process of hospitalization; Hypersensitivity reaction to analgesic drugs occurred; The diagnosis were changed during the further investigations

#### **Age**

From **18 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **120**

#### **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 Isfahan University of Medical Sciences

###### **Street address**

Hezar jirib street, Isfahan Uuniversity of Medical Science

###### **City**

Isfahan

###### **Postal code**

##### **Approval date**

2016-02-03, 1394/11/14

##### **Ethics committee reference number**

395024

### **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**

duration of hospitalization

##### **Timepoint**

at the end of the intervention

##### **Method of measurement**

minutes by timer

#### **2**

##### **Description**

severity of pain

##### **Timepoint**

before and 3-, 5-, 10- and 30-minute after the intervention

##### **Method of measurement**

visual analogue scale

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

At the beginning 50 microgram ( $\mu\text{g}$ ) fentanyl was infused for all of the patients. First group was received mask of oxygen. Patients were able to remove the mask if their pain was relief. If the pain was not relief after 30 minutes, 50  $\mu\text{g}$  fentanyl was infused again. Finally, if the patient was still suffering from pain, another usual pain relieving agent such as Ketorolac and Ketamine was used to decrease the severity of patient's pain.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

At the beginning 50 microgram ( $\mu\text{g}$ ) fentanyl was infused for all of the patients. First group was received mask of oxygen. Patients were able to remove the mask if their pain was relief. If the pain was not relief after 30 minutes, 50  $\mu\text{g}$  fentanyl was infused again. Finally, if the patient was still suffering from pain, another usual pain relieving agent such as Ketorolac and Ketamine was

used to decrease the severity of patient's pain.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Alzahra hospital

**Full name of responsible person**

Dr Omid Ahmadi

**Street address**

Alzahra hospital, Sofeh street, Isfahan, Iran

**City**

Isfahan

### 2

#### Recruitment center

**Name of recruitment center**

Kashani hospital

**Full name of responsible person****Street address****City**

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Isfahan University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research, Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezarjirib st, Isfahan, Iran

**City**

Isfahan

**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, Isfahan 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**

Department of Emergency Medicine, Isfahan University of Medical Sciences

**Full name of responsible person**

Omid Ahmadi

**Position**

Emergency Medicine specialist

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

Department of Emergency Medicine, Alzahra hospital, Sofeh street, Isfahan, Iran

**City**

Isfahan

**Postal code****Phone**

+98 31 3261 3464

**Fax****Email**

omid.ep@med.mui.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Department of Emergency Medicine, Isfahan University of Medical Sciences

**Full name of responsible person**

Omid Ahmadi

**Position**

Emergency Medicine specialist

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

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**Web page address**

## Person responsible for updating data

### Contact

## 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*