

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+O₂) 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 mask of Entonox and the second group 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 were 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 (μg) 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 μg 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 (μg) 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 μg 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**

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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