# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Sep 2026

## Evaluation of the effect of Penthrox spray as an analgesic compared to Morphine in patients with upper or lower limb fracture: A clinical trial study

## Protocol summary

**Study aim**
Determining the effectiveness of Pentrox spray as an analgesic in upper or lower limb fractures pain in the emergency room.

**Design**
A trpile-blinded randomized phase 3 clinical trial with parallel groups

**Settings and conduct**
This study will be conducted in the emergency department of Al-Zahra and Kashani Hospital in Isfahan, Iran, on 25 patients. The patients will be treated with the drug packages predetermined by the study supervisor (supervisor). The drug packages are completely similar in terms of shape, and the patient and the investigator are not aware of the contents of the packages. Forms are completed by the investigator, who is not aware of the contents of the packages. In the data analysis stage, the analysis will be done by the project advisor and the investigator, who are not aware of the contents of the drug packages, and only the patient group (group 1 or 2) will be used for data analysis.

**Participants/Inclusion and exclusion criteria**
Patients with upper or lower limb fracture who hemodynamically unstable and those who hadn't informed consent

**Intervention groups**
Methoxyflurane is a fluorinated hydrocarbon inhalation agent available in 3 cc ampoules used in the Pentorax inhaler as an intervention. To administer methoxyflurane, we use a Pentorax inhaler with activated charcoal. The patient is asked to cover the diluting valve with his finger, place the inhaler mouthpiece in his mouth, and exhale through the mouthpiece or nose. Each patient is prescribed a maximum of 1 ampoule, equivalent to 3 ccs without supplemental oxygen. Morphine is an opioid pain reliever injected intravenously at 0.1 mg per kilogram of weight as an infusion for the control group. Every time intravenous morphine is used, the vital signs, including pulse, heart rate, temperature, and Oxygen saturation percentage, Are recorded.

**Main outcome variables**
Determining mean pain in trauma patients

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20230302057587N1**
Registration date: **2023-04-17, 1402/01/28**
Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**
Update count: **0**

**Registration date**
2023-04-17, 1402/01/28

**Registrant information**

**Name**
mohammad golban

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 31 3435 3008

**Email address**
mohammad_golban@yahoo.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-04-21, 1402/02/01

**Expected recruitment end date**

2023-06-20, 1402/03/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of Penthrox spray as an analgesic compared to Morphine in patients with upper or lower limb fracture: A clinical trial study

**Public title**

Analgesic effect of Penthrox spray in patients with upper or lower limb fracture

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with upper or lower fracture Age between 20 to 55 Informed consent to participation in the study

**Exclusion criteria:**

Impaired level of consciousness (Glasgow coma score less than 15) Hemodynamic disturbance during use (systolic blood pressure less than 90 mmHg, peripheral rate less than 60 beats per minute, breathing rate less than 8 per minute, blood oxygen saturation less than 90% Use of substances, alcohol, sedatives or pain relievers in the past 48 hours History of taking Monoamine Oxidase Inhibitors, Tricyclic Antidepressants, Serotonin Receptors Reuptake Inhibitors, Phenothiazines, and sleeping pills Suffering from chronic diseases such as congenital or acquired heart diseases, chronic liver failure, bile duct diseases, kidney failure and chronic lung disease according to history and clinical examination. Allergy to Morphine or Penthrox Weight more than 100 kg Lack of informed consent Patient non-cooperation

**Age**

From **20 years** old to **55 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **25**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using Permuted block randomization method, patients are placed in one of the two study groups and receive the intervention related to the same group.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The participants, the principal investigator, the health care personnel (doctors, nurses, physiotherapists, etc.) responsible for the patient's care, the consultant professor, and the analyst were blinded.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethical Committee of Isfahan University of Medical Sciences

**Street address**

Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services

**City**

Isfahan

**Province**

Isfehan

**Postal code**

81746-73461

**Approval date**

2020-03-30, 1399/01/11

**Ethics committee reference number**

IR.MUI.MED.REC.1399.014

## Health conditions studied

### 1

**Description of health condition studied**

Analgesics

**ICD-10 code**

Y45.0

**ICD-10 code description**

Opioids and related analgesics

## Primary outcomes

### 1

**Description**

Pain number in the Visual Analogue Scale (VAS)

**Timepoint**

10, 20, 30, 60 minutes after receiving the medicine

**Method of measurement**

The Visual Analogue Scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Methoxyflurane, a fluorinated hydrocarbon inhalation agent available in 3 cc ampoules, used in the Pentorax inhaler (manufactured by MDI, Melbourne, Australia). Three cc of methoxyflurane are poured into each spray. If the diluting valve is open, the spray emits 0.2-0.4%, and if it is closed, it releases 0.5-0.7% methoxyflurane. It also has an oxygen port. To administer methoxyflurane, we use a Pentorax inhaler with activated charcoal. The patient is asked to cover the diluting valve with his finger and put the nebulizer mouthpiece in his mouth, and exhale through the mouthpiece or nose. A maximum of 1 vial (equivalent to 3 ccs) is prescribed to each patient without supplemental oxygen. Each care provider administers methoxyflurane to two patients in his shift. Each inhaler is used only for one patient. Vital signs, including pulse rate, heart rate, oxygen saturation percentage, and body temperature, are recorded in each inhalation of Penthrox. All patients undergo cardiac monitoring, and if changes are made, they are recorded with an electrocardiogram. Any side effects caused by the drug, including hypotension, bradycardia, convulsions, decreased level of consciousness, itching, skin rash, and respiratory depression, are recorded. Every ten minutes, if the patient's pain level is 5.10, intravenous fentanyl with a dose of 1 microgram per kilogram of weight will be prescribed as a rescue dose. At the end of the meeting, the rescue dose of fentanyl will be recorded.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Intravenous morphine at a dose of 0.1 mg per kilogram of weight (manufactured by Daro Pakhsh Co., Tehran, Iran) will be infused. Every time the intravenous morphine is used, the vital signs including pulse rate, heart rate, degree of temperature and percentage of oxygen saturation are recorded. All patients undergo cardiac monitoring, and if changes are made, they are recorded with an electrocardiogram. Any side effects caused by the drug, including hypotension, bradycardia, convulsions, decreased level of consciousness, itching, skin rash, and respiratory depression are recorded. Every ten minutes, if the patient's pain level is 5.10, intravenous fentanyl with a dose of 1 microgram per kilogram of weight will be prescribed as a rescue dose, and at the end of the meeting, the rescue dose of fentanyl will be recorded.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Al-Zahra Hospital
**Full name of responsible person**
Dr. Seyed Mohammad Reza Safavi
**Street address**
Safeh Street, Al-Zahra Medical Education Center, Isfahan
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746-75731
**Phone**
+98 31 3620 2020
**Email**
Alzahra@mui.ac.ir

### 2

**Recruitment center**

**Name of recruitment center**
Ayatollah Kashani Hospital
**Full name of responsible person**
Dr. Mojtaba Rahimi
**Street address**
Kashani St
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746-75731
**Phone**
+98 31 3233 0091
**Email**
AyatollahKashani@mui.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Dr. Gholamreza Asgari
**Street address**
Hazar jarib St., Isfahan University of Medical Sciences and Health Care Services
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746-73461
**Phone**
+98 31 3668 7898
**Email**
research@mui.ac.ir

**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Esfahan University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Mohammad Gulban
**Position**
Residence
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Emergency Medicine
**Street address**
Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746-73461
**Phone**
+98 31 3668 7898
**Email**
mohammad_golban@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Reza Azizkhani
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Emergency Medicine
**Street address**
Ehsan Complex, Shkoufeh Alley, Gulkhane St., Khane Isfahan
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746-73461
**Phone**
+98 31 3620 2085
**Email**
Azizkhani.reza@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Mohammad Golban
**Position**
Specialist
**Latest degree**
Specialist
**Other areas of specialty/work**
Emergency Medicine
**Street address**
B161, zeitoon complex, razmandegan blvd, robot st.
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746-73461
**Phone**
+98 31 3435 3008
**Fax**
**Email**
mohammad_golban@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
There is no further information
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available