

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jul 2026

### A clinical trial to evaluate the effect of inhaled pharmaceutical Pentrox (Methoxyflurane) compared with the placebo group on pain in patients with limb fracture

#### Protocol summary

##### Summary

Objectives: Following the accident, between emergency responders get to the patients and reach them to the hospital, there is a considerable time that most patients complain is pain during this interval. The aim of this study was to evaluate the analgesic effect of inhaled Pentrox as a treatment for injuries caused by the fracture. METHODS: This study is performed at the Baqiyatallah University of medical sciences. This is a triple-blind randomized clinical trial. In this study, the patients, measuring the outcomes of study participants (researchers) or Data Monitoring Committee (analyzers) of the patients unaware about intervention. The study included 100 patients with limb fractures were transferred by ambulance to the emergency ward. Patients randomly using a table of random numbers in the two groups (each group 50 patients). Methoxyflurane inhalation drug in intervention group (Pentrox) and placebo in controls will be used. The main outcome of this study is the pain and assess using standard criteria (visual analog scale (VAS)). Duration of improves patients outcomes is another outcome in this study. This clinical trial is a phase 2 study. Exclusion criteria are: 1. The history of allergies 2. History of liver disease 3. The history of kidney disease 4. Liver and kidney disease 6. Trauma and rupture of the liver and kidneys

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015111724799N3**

Registration date: **2015-12-09, 1394/09/18**

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

Last update:

Update count: **0**

##### Registration date

2015-12-09, 1394/09/18

##### Registrant information

###### Name

Masoud Saghafinia

###### Name of organization / entity

Baqiyatallah university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8126 3207

###### Email address

dr\_saghafi@bmsu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Baqiyatallah University of medical sciences and Khosro Medisa Teb

##### Expected recruitment start date

2014-04-21, 1393/02/01

##### Expected recruitment end date

2016-05-21, 1395/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial to evaluate the effect of inhaled pharmaceutical Pentrox (Methoxyflurane) compared with the placebo group on pain in patients with limb fracture

##### Public title

Effect of inhaled pharmaceutical Pentrox

(Methoxyflurane) on pain of limb fracture

#### **Purpose**

Supportive

#### **Inclusion/Exclusion criteria**

Inclusion criteria: Patients older than 18 years who have had limb fractures. Exclusion criteria: Patients with a history of allergy to inhaled medications, severe injuries, including a ruptured liver and the kidneys, liver disease, kidney disease, patient dissatisfaction and age under 18 and over 80 years as well as patients with a decreased level of consciousness

#### **Age**

From **18 years** old to **80 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)**

Triple 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 Baqiyatallah University of Medical Sciences

##### **Street address**

Postal code: 1435917541, Mollasadra, St - Sheikh Bahaee, St, Tehran

##### **City**

Tehran

##### **Postal code**

1435917541

#### **Approval date**

2009-11-03, 1388/08/12

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

ir.bssu.rec.1388.7

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Sequelae of fracture of arm

#### **ICD-10 code**

T92.1

#### **ICD-10 code description**

Sequelae of injury classifiable to S42.-, S52.- and T10

### **2**

#### **Description of health condition studied**

Sequelae of other fractures of lower limb

#### **ICD-10 code**

T93.2

#### **ICD-10 code description**

Sequelae of injury classifiable to S82.-, S92.- and T12

## **Primary outcomes**

### **1**

#### **Description**

Pain

#### **Timepoint**

Before intervention, 5, 10, 20 and 30 minutes after intervention

#### **Method of measurement**

Questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

Times of pain reduction

#### **Timepoint**

Before intervention, 5, 10, 20 and 30 minutes after intervention

#### **Method of measurement**

Questionnaire

## **Intervention groups**

### **1**

#### **Description**

Intervention 2: Placebo

#### **Category**

Placebo

### **2**

#### **Description**

Intervention 1: Pentrox inhaler, the recommended dose is 6 milliliters, one time. It is manufactured and marketed by Medical Developments International (Melbourne, Victoria, Australia). Pentrox is known chemically as 2, 2-Dichloro-1, 1-Difluoroethyl methyl Ether. Brand of Pentrox is Methoxyflurane. How to use: A cylindrical whistle-like tube with a hole near the mouthpiece.

#### **Category**

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emergency department of Baqiyatallah university of medical sciences

##### Full name of responsible person

Masoud Saghafeinia

##### Street address

Postal code: 1435917541, Mollasadra, St - Sheikh, St, Tehran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Baqiyatallah University of Medical Sciences

##### Full name of responsible person

Hamid Reza Rasouli

##### Street address

Postal code: 1435917541, Mollasadra, St - Sheikh Bahaee, St, Tehran

##### 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 for research, Baqiyatallah 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

Baqiyatallah university of medical sciences

##### Full name of responsible person

Masoud Saghafeinia

##### Position

Faculty member/Anesthesiologist

#### Other areas of specialty/work

##### Street address

Postal code: 1435917541, Mollasadra, St - Sheikh Bahaee, St, Tehran

##### City

Tehran

##### Postal code

##### Phone

+98 21 8805 3766

##### Fax

##### Email

dr\_saghafi@bmsu.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Baqiyatallah University of Medical Sciences

##### Full name of responsible person

Masoud Saghafeinia

##### Position

Faculty member/Anesthesiologist

##### Other areas of specialty/work

##### Street address

Postal code: 1435917541, Mollasadra, St - Sheikh Bahaee, St, Tehran

##### City

Tehran

##### Postal code

##### Phone

+880 53766

##### Fax

##### Email

dr\_saghafi@bmsu.ac.ir

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Baqiyatallah university of medical sciences

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Masoud Saghafeinia

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##### 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*