Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Public title

Effect of inhaled pharmaceutical Penthrox

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

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emergency department of Baqiyatallah university of medical sciences

Full name of responsible person
Masoud Saghafinia

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

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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 Saghafinia

Position
Faculty member/Anesthesiologist

Other areas of specialty/work

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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