

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparing the efficacy and adverse effects of oxycodone and morphine sulfate in isolated limb trauma patients, admitted to emergency department of Imam Khomeini hospital, between 2011 and 2012 period

#### Protocol summary

##### Summary

To compare the efficacy of oxycodone and morphine sulfate a double blinded, randomized, clinical trial study will be done. After obtaining informed consent, forty adult patients with acute lower limb trauma who are eligible for this study will be randomized to two groups. The control group will receive 5 milligrams of morphine sulfate intravenous injection and placebo tablet and the intervention group will receive 5 milligrams oxycodone hydrochloride tablet and placebo injection. Pain severity will be assessed by NRS (Numerical pain Rating Scale) scoring system. At times 0, 30', 60' of analgesic administration pain severity, vital signs and adverse effects of analgesics such as lethargy, nausea, vomiting and itching will be assessed and registered in data collection sheets. All patients older than 14 years old with acute lower limb trauma who are admitted to Emergency department of Imam Hospital could be eligible for study however patients with past history of allergy to opioid, chronic renal/respiratory/liver disease, recent use of opioid, altered mental state, head trauma and pregnant patients will be excluded from study. SPSS software will be used for data analysis.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201204089387N2**  
Registration date: **2013-03-26, 1392/01/06**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-03-26, 1392/01/06

#### Registrant information

##### Name

Mohammad Jalili

##### Name of organization / entity

Tehran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

00982166418595, 00982166418985

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#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Science

#### Expected recruitment start date

2012-08-19, 1391/05/29

#### Expected recruitment end date

2012-12-19, 1391/09/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing the efficacy and adverse effects of oxycodone and morphine sulfate in isolated limb trauma patients, admitted to emergency department of Imam Khomeini hospital, between 2011 and 2012 period

#### Public title

Comparing the efficacy of morphine sulfate and oxycodone in pain management

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: acute lower limb trauma  
Exclusion criteria: Patients younger than 14 or older than 90 years old, recent use of opioid, advanced liver/respiratory/renal diseases, head trauma, altered mental state, allergy to opioid, pregnancy

#### Age

From **14 years** old to **90 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **40**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double 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 TEHRAN UNIVERSITY OF  
MEDICAL SCIENCE

##### Street address

KESHAVARZ BLVD, CENTRAL BUILDING OF TEHRAN  
UNIVERSITY OF MEDICAL SCIENCE

##### City

TEHRAN

##### Postal code

#### Approval date

2012-05-23, 1391/03/03

#### Ethics committee reference number

91-01-30-15974-54352

## Health conditions studied

### 1

#### Description of health condition studied

Acute lower limb injury

#### ICD-10 code

s70, s72,

#### ICD-10 code description

Superficial injury of hip and thigh, Fracture of femur,  
Dislocation, sprain and strain of joint and ligaments of

hip, Injury of muscle and tendon at hip and thigh level,  
Crushing injury of hip and thigh, Traumatic amputation of  
hip and thigh, Superficial

## Primary outcomes

### 1

#### Description

Pain severity

#### Timepoint

0, 30 and 60 minutes after administration of analgesic

#### Method of measurement

asking patients, using NRS score

## Secondary outcomes

### 1

#### Description

Side effects

#### Timepoint

0, 30 and 60 minute after administration of analgesic

#### Method of measurement

asking patient, using questionnaire

### 2

#### Description

Blood pressure

#### Timepoint

Zero, 30, and 60 minutes after administration of  
analgesic

#### Method of measurement

Checking blood pressure, using appropriate cuff

### 3

#### Description

Nausea and vomiting

#### Timepoint

Zero, 30 and 60 minutes after administration of  
analgesic

#### Method of measurement

Asking patient, using questionnaire

### 4

#### Description

Drowsiness

#### Timepoint

Zero, 30 and 60 minutes after administration of  
analgesic

#### Method of measurement

Asking patient, using questionnaire

## Intervention groups

### 1

#### Description

Oxycodone hydrochloride; manufactured by SOHA

company; 5 milligrams single dose; oral; in intervention group

**Category**

Treatment - Drugs

**2**

**Description**

Placebo (distilled water); manufactured in Daroupakhsh; single dose; intravenous injection; in intervention group

**Category**

Treatment - Drugs

**3**

**Description**

Morphine sulfate; manufactured in Daroupakhsh; 5 milligrams single dose; intravenous injection; in control group

**Category**

Treatment - Drugs

**4**

**Description**

Placebo; manufactured by SOHA company; single dose; oral; in control group

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Emergency Department of Imam Khomeini Hospital

**Full name of responsible person**

Mrs.Amani

**Street address**

Keshavarz Blvd, Tehran, Iran

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research, Tehran University of Medical Sciences

**Full name of responsible person**

Dr Yunesian

**Street address**

TUMS Central Building, Keshavarz Blvd, Ghods St.

**City**

Tehran, Iran

**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, Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Jalili

**Position**

Vice Chancellor for Education

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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M.D

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**Fax**

## 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*