

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### comparison of analgesic effect of memantin plus morphin with morphin in patient with lower limb trauma

#### Protocol summary

##### Summary

Objectives: Comparing the analgesia effect of morphine and morphine plus memantin in patients with lower limb trauma. Inclusion Criteria: Fracture in lower extremity; GCS=15; VAS $\geq$ 6 ; ability to talk; stable hemodynamic. Exclusion Criteria: age>65 and age <18; Opium addiction; Psychological disorder; analgesia administration before admission in Emergency department; chronic therapy with analgesic drugs; sensitivity to morphine or memantin; unable to understand the VAS concept; pregnancy; necessity to nerve block; unwilling to take part in the intervention; refuse to continue the intervention; major trauma which is life threatening or causing defects; any history of chronic disease. The population of study is included in patients suffering lower extremity fracture, who are admitted suffering severe pain(VAS $\geq$ 6), requiring analgesia. Sample of Study: According to population of study, 333 patients will be studied in each group. Intervention of Study: Investigation of the analgesic effect of Memantin in patients suffering Limb Trauma. Outcome: The effect on Pain Severity 0, 60, 120, 240, 480 and 720 minutes after treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201404107751N3**  
Registration date: **2014-11-28, 1393/09/07**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-11-28, 1393/09/07

##### Registrant information

##### Name

Davood Farsi

##### Name of organization / entity

TUMS

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6652 5327

##### Email address

dfarsi@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Iran University of Medical Sciences

##### Expected recruitment start date

2014-07-23, 1393/05/01

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparison of analgesic effect of memantin plus morphin with morphin in patient with lower limb trauma

##### Public title

Pain control in Lower limb traumatic patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: Fracture in lower extremity; GCS=15; VAS $\geq$ 6 ; ability to talk; stable hemodynamic. Exclusion Criteria: age>65 and age <18; Opium addiction; Psychological disorder; analgesia administration before admission in Emergency department; chronic therapy

with analgesic drugs; sensitivity to morphine or memantin; unable to understand the VAS concept; pregnancy; necessity to nerve block; unwilling to take part in the intervention; refuse to continue the intervention; major trauma which is life threatening or causing defects; any history of chronic liver; kidney; lung; cardiac disease

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **1000**

#### 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

Iran University of Medical Sciences

##### Street address

Hemmat highway, next to Milad Hospital

##### City

Tehran

##### Postal code

#### Approval date

2014-04-26, 1393/02/06

#### Ethics committee reference number

93/105/373/5

## Health conditions studied

### 1

#### Description of health condition studied

Pain in limb

#### ICD-10 code

M79.6

#### ICD-10 code description

Pain in limb

## Primary outcomes

### 1

#### Description

Pain Severity

#### Timepoint

0, 60, 120, 240, 480 and 720 minutes after treatment

#### Method of measurement

Administration of Visual Analogue Scale and asking the patient to determine the severity of pain

## Secondary outcomes

### 1

#### Description

Side effects and changes in vital signs

#### Timepoint

30, 60 and 120 minutes after treatment

#### Method of measurement

Patient monitoring

## Intervention groups

### 1

#### Description

first group:morphin+memantin 10 mg

#### Category

Treatment - Drugs

### 2

#### Description

second group:morphin+memantin 5 mg

#### Category

Treatment - Drugs

### 3

#### Description

third group:morphin +placebo

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emergency Department of Hazrate Rasool (S)

Educational-Therapeutic Centre

##### Full name of responsible person

Esmat Shabani, MD

##### Street address

Emergency department, Hazrate Rasool hospital,

Niyayesh street, Sattarkhan

##### City

Tehran

## 2

### Recruitment center

**Name of recruitment center**

Emergency Department of Haftetir Hospital

**Full name of responsible person**

Esmat Shabani, MD

**Street address**

Rajae st.

**City**

Shahre Rey

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Iran University of Medical Sciences

**Full name of responsible person**

Seyyed Ali Javad Mousavi, MD

**Street address**

Shahid Hemmat Highway, next to Milad Hospital

**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, Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Saeid Abbasi, MD

**Position**

Emergency Medicine Specialist/ Assistant Professor

**Other areas of specialty/work****Street address**

Emergency Departement of Rasool Akram Hospital

**City**

Tehran

**Postal code**

14648

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eshabani1222@yahoo.com

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### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Davood Farsi, MD

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Emergency Medicine Specialist/ Assistant Professor

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### Person responsible for updating data

#### Contact

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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*