

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The comparative study of clinical efficacy and palliative effect of adding Diazepam and Methocarbamol to Morphine in emergency department patients with spinal trauma

#### Protocol summary

##### Study aim

Efficacy of adding Diazepam and Methocarbamol to standard treatment in spinal trauma

##### Design

Three arm triple blinded, parallel group, randomized clinical trial

##### Settings and conduct

Scientist prepare and label the drugs. Patients with spinal trauma who admitted in Alzahra and Kashani hospital (Isfahan city) divided in 3 groups after randomization and study manager start treating patient due to randomized numeric table; without knowing about treatment protocol. Patients in different groups receive below treatments: group 1: 10 minutes infusion of 0.1 mg/kg Morphine diluted in 100 ml normal saline group 2: 10 minutes infusion of 0.1 mg/kg Morphine and 0.15 mg/kg Diazepam diluted in 100 ml normal saline group 3: 10 minutes infusion of 0.1 mg/kg Morphine and 1000 mg Methocarbamol diluted in 100 ml normal saline Study observer check and record complications and pain severity with VAS (Visual Analog Scale) score in beginning of the study and after 30 minutes, 1 hour and 2 hour of treatment; without knowing about treatment protocol. Statistical analyzer, Analyze the study without knowing about patients group and give the results to researcher for conclusion.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-65 years old; normal blood pressure; no malignancy and underling disease Non-Inclusion criteria: drug user; history of Opiods, Non-steroidal anti-inflammatory drugs (NSAID's) and muscle relaxant drug use in past 24 hours

##### Intervention groups

Patients are divided in 3 group after randomization: group 1) receive IV Morphine group 2) receive IV Morphine and Diazepam group 3) receive IV Morphine and Methocarbamol group

#### Main outcome variables

Diazepam and Methocarbamol efficiency in patient pain control

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130108012072N12**

Registration date: **2020-11-27, 1399/09/07**

Registration timing: **prospective**

Last update: **2020-11-27, 1399/09/07**

Update count: **0**

##### Registration date

2020-11-27, 1399/09/07

##### Registrant information

##### Name

Mehrdad Esmailian

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3629 3482

##### Email address

m\_esmailian@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-21, 1399/10/01

##### Expected recruitment end date

2021-09-23, 1400/07/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The comparative study of clinical efficacy and palliative effect of adding Diazepam and Methocarbamol to Morphine in emergency department patients with spinal trauma

**Public title**  
Diazepam and Methocarbamol in spinal trauma efficacy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Visual Analog Scale>4 No neurological signs No malignancy and underling disease No sensitivity to Morphine or Diazepam or Methocarbamol Blood Pressure >=110/70 mm Hg  
**Exclusion criteria:**  
Drug user History of Opioids, Non-steroidal anti-inflammatory drugs (NSAID's) and muscle relaxant drug use in past 24 hours

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

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

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

**Sample size**  
Target sample size: **105**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple randomization with table of random numbers. In this study, based on predefined 3-digit number (001,002,003,...) randomization table, blindly choose one number, then upper and below numbers choose vertically as treatment code for each patient. After ending the the numbers, manager blindly choose another number again and apply the upper and below numbers for each patient. Every 3-digit number from 001 to 105, marked as one randomized treatment protocol (35 number for treatment protocol "A", 35 number for treatment protocol "B" and 35 number for treatment protocol "C"); study manager doesn't knowing about drug that use in each protocol. Chosen numbers must be lesser than sample size and greater numbers will be deleted. This protocol continued until all patients who meet inclusion criteria get a random number. Due to this method, patients stay on one treatment group, without knowing about treatment protocol.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
Drugs are preparing with scientist and labeled (scientist is blinded to patient's treatment group and efficacy or complications of each groups). Patients are selected with randomized numeric table and don't aware about treatment protocol. Manager use treatment pathway base on patient randomization; blinded about drug that be used and record result and complications. Statistical analyst, analyses the study without knowing about patients group and give the results to researcher for conclusion.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Ethics committee of Isfahan University of Medical Sciences

**Street address**  
Alzahra general hospital, Sofeh blv., Isfahan

**City**  
Isfahan

**Province**  
Isfahan

**Postal code**  
8175898595

**Approval date**  
2020-05-31, 1399/03/11

**Ethics committee reference number**  
IR.MUI.MED.REC.1399.122

**Health conditions studied**

**1**

**Description of health condition studied**  
Spinal trauma

**ICD-10 code**  
S34.1

**ICD-10 code description**  
Other and unspecified injury of lumbar and sacral spinal cord

**Primary outcomes**

**1**

**Description**  
Pain severity score with Visual Analog Scale

### **Timepoint**

Study beginning, 30 minutes and 1 hour and 2 hours after treatment

### **Method of measurement**

Visual Analog Scale

## **2**

### **Description**

Drug complications

### **Timepoint**

Study beginning, 30 minutes and 1 hour and 2 hours after treatment

### **Method of measurement**

Standard questionnaire form (Brief Medication Questionnaire)

## **Secondary outcomes**

### **1**

### **Description**

Insufficient pain control

### **Timepoint**

1 hour after treatment

### **Method of measurement**

Visual Analog Scale

## **Intervention groups**

### **1**

### **Description**

Intervention group 1: 0.1 mg/kg Morphine (osvahpharma) diluted in 100 ml normal saline in 10 minutes infusion

### **Category**

Treatment - Drugs

### **2**

### **Description**

Intervention group 2: 0.1 mg/kg Morphine (osvahpharma) and 0.15 mg/kg Diazepam (caspitantamin) diluted in 100 ml normal saline in 10 minutes infusion

### **Category**

Treatment - Drugs

### **3**

### **Description**

Intervention group 3: 0.1 mg/kg Morphine (osvahpharma) and 1000 mg Methocarbamol (caspitantamin) diluted in 100 ml normal saline in 10 minutes infusion

### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

### **Recruitment center**

#### **Name of recruitment center**

Alzahra General Hospital

#### **Full name of responsible person**

Mehrdad Esmailian

#### **Street address**

Alzahra general hospital, sofeh Blv

#### **City**

Isfahan

#### **Province**

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8175898595

#### **Phone**

+98 31 3620 2085

#### **Fax**

#### **Email**

m\_esmailian@med.mui.ac.ir

#### **Web page address**

### **2**

### **Recruitment center**

#### **Name of recruitment center**

Kashani hospital

#### **Full name of responsible person**

Mehrdad Esmailian

#### **Street address**

Kashani hospital, Kashani street

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

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## **Sponsors / Funding sources**

### **1**

### **Sponsor**

#### **Name of organization / entity**

Esfahan University of Medical Sciences

#### **Full name of responsible person**

Shaghayegh Haghjoo

#### **Street address**

Isfahan University of Medical Sciences, Hezarjerib Ave., Azadi square, Isfahan, Iran

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

8175898595

#### **Phone**

+98 31 3620 2085

#### **Email**

sh\_haghjoo@med.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**

Mehrdad Esmailian

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Hezarjerib Av., Isfahan

**City**

Isfahan

**Province**

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**Postal code**

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## Person responsible for scientific inquiries

**Contact**

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Esfahan University of Medical Sciences

**Full name of responsible person**

Mehrdad Esmailian

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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Esfahan University of Medical Sciences

**Full name of responsible person**

Mehrdad Esmailian

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Whole of data after coding

**When the data will become available and for how**

**long**

Accessibility after 2022

**To whom data/document is available**

Everyone

**Under which criteria data/document could be used**

For seemingly studies data released to academic chairman's

**From where data/document is obtainable**

Isfahan University of Medical Sciences

**What processes are involved for a request to access data/document**

Emailing to [m\\_esmailian@med.mui.ac.ir](mailto:m_esmailian@med.mui.ac.ir)

**Comments**