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 Opiods, 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

Isfehan

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 (caspiantamin) 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 (caspiantamin) 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
Isfehan
Postal code
8175898595
Phone
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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
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Street address
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8175898595
Phone
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Email
m_esmailian@med.mui.ac.ir

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
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Postal code
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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

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+98 31 3629 3482

Email

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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

Comments