

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Efficacy of Methocarbamol-Morphine and Diazepam-Morphine to Reduce Acute Low Back Pain in Adult Patients in the Emergency Department

Protocol summary

Study aim

Comparison of the Efficacy of the Addition of Methocarbamol or Diazepam to Morphine to Reduce Acute Low Back Pain in the Emergency Department

Design

Randomized double-blind clinical trial

Settings and conduct

It is conducted in 3 university hospitals. The syringes are similar in volume and color.

Participants/Inclusion and exclusion criteria

Adult patients (18 years or older) were included with acute low back pain (LBP) which was aggravating or commencing in the last 2 weeks. Exclusion Criteria consisted of renal or hepatic insufficiency, pregnancy or breastfeeding, and unstable vital signs (pulse rate <50 or >150 beats/min, systolic blood pressure <90), and patients who had already received analgesics in the past 24 hours.

Intervention groups

Group 1: Methocarbamol 100mg/10ml intravenous in 3 minutes infusion, then morphine 6 milligram (mg) was prescribed. Group 2: Diazepam 5 mg diluted with 9 milliliter normal saline and infused during 3 minutes then, morphine 6 mg intravenously was prescribed.

Main outcome variables

Comparison of the Efficacy of the Addition of Methocarbamol or Diazepam to Morphine to Reduce Acute Low Back Pain in the Emergency Department

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151113025025N4**

Registration date: **2020-08-09, 1399/05/19**

Registration timing: **prospective**

Last update: **2020-08-09, 1399/05/19**

Update count: **0**

Registration date

2020-08-09, 1399/05/19

Registrant information

Name

Maryam Bahreini

Name of organization / entity

Tehran University of Medical Sciences, Sina Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 1413

Email address

m-bahreini@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-20, 1399/05/30

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy of Methocarbamol-Morphine and Diazepam-Morphine to Reduce Acute Low Back Pain in Adult Patients in the Emergency Department

Public title

Comparison of the Efficacy of Methocarbamol-Morphine and Diazepam-Morphine to Reduce Acute Low Back Pain

in Adult Patients in the Emergency Department

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients (18 years or older) acute low back pain (LBP) aggravating or commencing in the last 2 weeks

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization of 4

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind (patients and outcome investigator)

Syringes have similar volume and color

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Emergency Department, Sina Hospital, Imam-Khomeini Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2018-11-13, 1397/08/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.564

Health conditions studied

1

Description of health condition studied

Low back pain

ICD-10 code

M54.4

ICD-10 code description

Lumbago with sciatica

Primary outcomes

1

Description

Comparison of the Efficacy of the Addition of Methocarbamol or Diazepam to Morphine to Reduce Acute Low Back Pain in the Emergency Department

Timepoint

0, 30 and 60 minutes

Method of measurement

Numeric rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Methocarbamol 100mg/10ml intravenous in 3 minutes infusion, then morphine 6 milligram (mg)

Category

Treatment - Drugs

2

Description

Intervention group: Diazepam 5 mg diluted with 9 milliliter normal saline and infused during 3 minutes then, morphine 6 mg intravenously

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Maryam Bahreini

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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3

Recruitment center

Name of recruitment center
Shariati Hospital
Full name of responsible person
Maryam Bahreini
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Emergency Department, Shariati Hospital, Jalal-e Al-e
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
Street address

Keshavarz Blv., Tehran, Iran
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Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
10
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
Tehran University of Medical Sciences
Full name of responsible person
Maryam Bahreini
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The article manuscript

When the data will become available and for how long

When the journal will permit

To whom data/document is available

To the reviewers of the article

Under which criteria data/document could be used

If they request by email.

From where data/document is obtainable

If they request by email, it will be responded by email.

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

If they request by email.

Comments