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
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Name of organization / entity
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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
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
Street address
Emergency Department, Sina Hospital, Imam-Khomeini Ave, Tehran, Iran
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Province
Tehran
Postal code
1336746911

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<th>Name of recruitment center</th>
<th>Full name of responsible person</th>
<th>Street address</th>
<th>City</th>
<th>Province</th>
<th>Postal code</th>
<th>Phone</th>
<th>Email</th>
<th>Web page address</th>
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<tbody>
<tr>
<td>1</td>
<td>Imam-Khomeini Hospital</td>
<td>Maryam Bahreini</td>
<td>Emergency Department, Imam-Khomeini Hospital, Keshavarz Blvd., Tehran, Iran</td>
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<td></td>
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<tr>
<td>2</td>
<td>Shariati Hospital</td>
<td>Maryam Bahreini</td>
<td>Emergency Department, Shariati Hospital, Jalal-e Al-e Ahmad Ave, Tehran, Iran</td>
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**Sponsors / Funding sources**

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<th>Full name of responsible person</th>
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<td>1</td>
<td>Tehran University of Medical Sciences</td>
<td>Dr. Mohammad Ali Sahraian</td>
<td></td>
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</tbody>
</table>

**Person responsible for general inquiries**

Contact
- Name of organization / entity: Tehran University of Medical Sciences
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**Person responsible for scientific inquiries**

Contact
- Name of organization / entity
Person responsible for updating data

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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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