

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of therapeutic effects and its outcomes with morphine against methadone in combination with diazepam and haloperidol in cancer patients with severe and chronic pain referred to emergency ward.

Protocol summary

Study aim

Comparison of therapeutic effects and its outcomes with morphine against methadone in combination with diazepam and haloperidol in cancer patients with severe and chronic pain referred to emergency ward.

Design

This study is double-blind and clinical trial. This study will be patients with cancer and severe pain complaints referred to the Emergency Hospital of Amir Al-Momenin and Valiasr Hospital in Arak. A total of 92 patients are enrolled in the study.

Settings and conduct

This study is double-blind and clinical trial. This study will be patients with cancer and severe pain complaints referred to the Emergency Hospital of Amir Al-Momenin and Valiasr Hospital in Arak. A total of 92 patients are enrolled in the study. We divide patients in two groups randomly. This study is clinical trial. Outcome evaluator and analyzer are blind (double blind). Outcome evaluator and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with metastatic disease of spine with pain complaints and severity of pain 7 and above referring to Emergency hospital of Amir Al-Momenin and Vali Asr Arak Hospital, non-allergic to benzodiazepine and haloperidol. Exclusion criteria: Unsatisfied patients, decreased consciousness at the time of referral or during the study, blood pressure drop of SBP <90 at the time of referral or during the study, there is any contraindication in the administration of opioid or Benzodiazepine or Haloperidol, patients with scores of pain less than 7, oxygen saturation below 92%, heart rate above 90 or under 60.

Intervention groups

We inject 5 milligram Metadon and 5 milligram Haloperidol in muscular and 10 milligram Diazepam

intravenous slowly for 5 minute in first group. We inject slowly 5 milligram Morphine sulphat intravenous.

Main outcome variables

Patient satisfaction-pain-drug complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N93**

Registration date: **2019-01-09, 1397/10/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-09, 1397/10/19**

Update count: **0**

Registration date

2019-01-09, 1397/10/19

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

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f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects and its outcomes with morphine against methadone in combination with diazepam and haloperidol in cancer patients with severe and chronic pain referred to emergency ward.

Public title

Comparison of therapeutic effects and its outcomes with morphine against methadone in combination with diazepam and haloperidol in cancer patients with severe and chronic pain referred to emergency ward.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with metastatic disease of spine with pain complaints and scurvy of pain 7 and above referring to Emergency hospital of Amiralmomenin and Vali Asr arak Hospital Non-allergic to benzodiazepine and haloperidol

Exclusion criteria:

Unsatisfied patients Decreased consciousness at the time of referral or during the study Blood pressure drop of SBP <90 at the time of referral or during the study There is any contraindication in the administration of opioid or Benzodiazepine or Haloperidol Patients with scores of pain less than 7 Oxygen saturation below 92% Heart rate above 90 or under 60

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 92

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random number in division of groups in two groups A and B. Randomized patients are divided into two groups. Randomized allocation in clinical trial studies refers to the process of dividing participants into different groups randomly. Randomizing gives each participant equal odds for being placed in each of the groups. The candidate patients who enter the study are randomly assigned to the randomly assigned table of randomly assigned to the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is clinical trial. Outcome evaluator and analyzer are blind (double blind). Outcome evaluator and analyzer don't aware from grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee Arak University Of Medical Sciences

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

848176941

Approval date

2018-06-10, 1397/03/20

Ethics committee reference number

IR.ARAKMU.REC.1397.084

Health conditions studied**1****Description of health condition studied**

Cancer

ICD-10 code

C80.9

ICD-10 code description

Malignant neoplasm, primary site unspecified

Primary outcomes**1****Description**

Pain

Timepoint

1 and 24 hours after intervention

Method of measurement

Visual analog scale

2**Description**

Patient satisfaction

Timepoint

24 hours after intervention

Method of measurement

observation

3**Description**

Side effect of drugs

Timepoint

After intervention

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: We inject 5 milligram Metadon and 5 milligram Haloperidol in muscular and 10 milligram Diazepam intravenous slowly for 5 minute in first group.

Category

Treatment - Drugs

2**Description**

Intervention group: We inject slowly 5 milligram Morphine sulphat intravenous.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr Simin Najafgholian

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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2**Recruitment center****Name of recruitment center**

Amiralmomenin hospital

Full name of responsible person

Dr Simin Najafgholian

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Amiralmomenin hospital, Sardasht

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor For Research, Arak University Of Medical Science

Full name of responsible person

Dr Mohammad Arjmandzadegan

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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

Vice Chancellor For Research, Arak University Of Medical Science

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**

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Ramin Parvizrad

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Simin Najafgholian

Position

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Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Parouhan

Position

Resident of emergency medicine

Latest degree

Medical doctor

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Simin najafgholian

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

They have to write letters to the professors and the university

Comments