Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Does midazolam plus haloperidol enhance morphine analgesia in opium dependent patients? A randomized clinical trial

Protocol summary

Summary

Objectives: To investigate the efficacy of Intramuscular haloperidol plus midazolam as co-analgesics among opium dependent patients in the emergency department. Design: Double-blind, randomized, placebo-controlled trial. Setting and conduct: From September 2011 to September 2012, participants were randomly assigned in either group A or B. A nurse who was blinded to the participants was administered the drugs. Participants, including major eligibility criteria: Adult (18 years and older) patients who were opium dependent and had been admitted to the emergency department because of pain. Exclusion criteria: Age below 18 years; refuse to participation in the trial; inability to express or evaluate the pain (loss of consciousness, non-verbal patients due to articulation problems or mental decline); systolic blood pressure under 100 mm Hg; long QT interval in electrocardiogram and pregnancy. Intervention: Group A received morphine 0.05 mg/kg intravenously (IV) and a mixture of midazolam 2.5 mg and haloperidol 2.5 mg [diluted in 5 cc of distilled water, intramuscular (IM)]; group B received morphine 0.05 mg/kg IV and distilled water 5 cc, IM. Main outcome measures: 1. Pain intensity based on numeric rating scale from 0 to 10, before and 1, 3 and 6 hours following intervention 2. Total doses of morphine, administered in case of inadequate pain control, 3. Hemodynamic status and level of consciousness of participants.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041219971N2**
Registration date: **2016-05-14, 1395/02/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-14, 1395/02/25

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tehran University of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Does midazolam plus haloperidol enhance morphine analgesia in opium dependent patients? A randomized clinical trial

Public title

Does midazolam plus haloperidol enhance morphine effect in opium dependent patients?

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Adult (18 years and older) patients who were opium dependent and had been admitted to the emergency department because of pain. Exclusion criteria: Age below 18 years; refuse to participation in the trial; inability to express or evaluate the pain (loss of consciousness, non-verbal patients due to articulation problems or mental decline); systolic blood pressure under 100 mm Hg; long QT interval in electrocardiogram and pregnancy.

Age

From **18 years** old to **139 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **87**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poorsina Avenue, Keshavarz Boulevard.

City

Tehran

Postal code

Approval date

2011-09-23, 1390/07/01

Ethics committee reference number

1137435

Health conditions studied

1

Description of health condition studied

Opium dependence syndrome

ICD-10 code

F11.2

ICD-10 code description

Mental and behavioral disorders due to use of opioids : dependence syndrome

Primary outcomes

1

Description

Pain intensity

Timepoint

Pre-intervention and at 1,3,6 hours post intervention

Method of measurement

Numerical Rating Scale

2

Description

Morphine doses

Timepoint

1,3 and 6 hours post-intervention

Method of measurement

Total doses of morphine (mg)

Secondary outcomes

1

Description

Side effects

Timepoint

1,3and 6 hours post intervention

Method of measurement

Observation and clinical examination

Intervention groups

1

Description

Controls were received intravenous morphine 0.05 mg/kg and 5 cc of intramuscular distilled water.

Category

Treatment - Drugs

2

Description

Cases were received intravenous morphine 0.05 mg/kg and intramuscular mixture of haloperidol 2.5 mg plus midazolam2.5 mg diluted in 5 cc of distilled water.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mohammad Afzalimoghadam
Street address
Shahid Chamran highway, Bagherkhan avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Mohammad Afzalimoghadam
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Poorsina Avenue, Keshavarz Boulevard
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Tehran
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, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty