Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of the effect of addition of Ketamine, Lidocaine, Acetaminophen and Dexmedetomidine to morphine in the pain control of opium addicts after orthopedic surgery

Protocol summary

Study aim
Comparison of the effect of addition of ketamine, lidocaine and acetaminophen and dexmedetomidine to morphine in the pain control pump of opium addicts after orthopedic surgery

Design
The double blind clinical trial, consisting of 140 patients whom were randomly divided into 4 groups. The groups are parallel. The trial phase is 3.

Settings and conduct
Patients with opium addicts after orthopedic surgery at Valiasr hospital in Arak are divided into 4 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 20 to 60 years, ASA class 1 and 2 Non inclusion criteria: Dissatisfaction with studying, not accepting spinal anesthesia as a method of anesthesia, obesity, chronic pain, mental disorders, history of seizures, psychotropic drugs, daily use of painkillers (more than a week), sensitivity to drugs, upper respiratory infection, pregnancy, breastfeeding, hemodynamic instability

Intervention groups
Intervention Group 1: 1 milligram/ kilogram of Ketamine (Rotex Medica, Germany) will be added to morphine . Intervention Group 2: 15 milligram/kilogram of Acetaminophen (Coble Drug - Iran) will be added to morphine. Intervention Group 3: 1/5 milligram/kilogram of Lidocaine(Caspian Tamin Rasht-Iran) will be added to morphine. Intervention Group 4:1 microgram/kilogram of Dexmedetomidine (Exir Company) will be added to morphine.

Main outcome variables
Relaxation; average drug use; nausea and vomiting; pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N146**
Registration date: **2020-07-10, 1399/04/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-10, 1399/04/20**
Update count: **0**

Registration date
2020-07-10, 1399/04/20

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2021-05-22, 1400/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effect of addition of Ketamine, Lidocaine, Acetaminophen and Dexmedetomidine to morphine in the pain control of opium addicts after orthopedic surgery

Public title
The effect of addition of ketamine, lidocaine and acetaminophen and dexmedetomidine to morphine in the pain control of opium addicts

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 20 to 60 years old ASA class 1 and 2

Exclusion criteria:
Dissatisfaction with studying Not accepting spinal anesthesia as a method of anesthesia Obesity Chronic pain Mental disorders History of seizures Use psychotropic drugs Use of painkillers (more than a week) Sensitivity to drugs Upper respiratory infection Pregnancy Breastfeeding Existence of hemodynamic instability

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with envelopes into 4 groups of A and B and C and D . In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were mixed. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are mixed again and we pulled out another card. This process continued to reach a random sequence according to sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Outcome evaluator and analyzer and participant are blind (double blind). Outcome evaluator and analyzer and participant don't aware from grouping. Drug sets will be covered with foil. After calculating the amount, the required drugs are drawn in 50 ML syringes and prescribed at the desired dose.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics comittee of Arak University of Medical Sciences

Street address
Ethics comitte; Vice Chancellor for Research and Technology; Payambar Azam complex, Basij square; Sardasht

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2020-05-10, 1399/02/21

Ethics committee reference number
IR.ARAKMU.REC.1399.060

Health conditions studied

1

Description of health condition studied
Pain after orthopedic surgery

ICD-10 code
Z47.82

ICD-10 code description
Encounter for orthopedic aftercare following scoliosis surgery

Primary outcomes

1

Description
Relaxation

Timepoint
At 1, 6, 12 and 24 hours after connecting the pump

Method of measurement
Ramsy score

2

Description
Average drug use

Timepoint
24 hours after connecting the pump

Method of measurement
Observation

3

Description
Nausea and vomiting
Timepoint
At 1, 6, 12 and 24 hours after connecting the pump
Method of measurement
Observation

4

Description
Pain
Timepoint
At 1, 6, 12 and 24 hours after connecting the pump
Method of measurement
Visual pain analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: 1 mg/kg of Ketamine (produced by Rotex Medica company, Germany) will be added to morphine.
Category
Treatment - Drugs

2

Description
Intervention group 2: 15 mg/kg of Acetaminophen (produced by Coble Drug company, Iran) will be added to morphine.
Category
Treatment - Drugs

3

Description
Intervention group 3: 1.5 mg/kg of Lidocaine(produced by Caspian Tamin Rasht company-Iran) will be added to morphine.
Category
Treatment - Drugs

4

Description
Intervention group 4: 1 micro gram per kilogram of Dexmedetomidine (produced by Exir Company) will be added to morphine.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr Hesamodin Modir
Street address
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr Esmaeel Moshiri
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Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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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, the raw data file will be provided to researchers.
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 Hesamodin Modir
What processes are involved for a request to access data/document
They have to write letters to the professors and the university.
Comments