Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of ketamine and midazolam combination with ketamine and morphine for acute pain management at emergency department

Protocol summary

Study aim

Determination of the effect of ketamine-midazolam combination in pain management at emergency department with regard to ketamine adverse reactions when used alone and comparison of these two regimens with morphine

Design

In this double blind clinical trial study there are three study regimens:ketamine-midazolam, ketamine, and morphine which are used as pain management at emergency department in patients with moderate to severe pain. 168 patients according to the inclusion and excluding criteria enter the study and will be randomized by specifying a code and use of randomized numeric table.

Settings and conduct

patients are selected at emergency department who have moderate to severe pain. study regimens are prefilled in syringes with special blinded codes administered to the patients by the nurse.

Participants/Inclusion and exclusion criteria

inclusion criteria:Patients with acute pain (onset within a week) including traumatic pain, non-traumatic musculoskeletal pain, neuropathic pain, low back pain, pain due to renal stone with with severity of point 5 or greater in numeric rating scale who need morphine for pain reduction, age range:18 to 55 yrs, exclusion criteria: pregnancy and lactation, allergy to morphine, ketamin and midazolam, brain problems, wight less than 46 or greater than 115 kg, unstable vital signs, elevated ICP, chronic pain, renal or hepatic failure, alcohol or substance abuse.

Intervention groups

1-midazolam-ketamine, 2-ketamine, 3-morphine

Main outcome variables

1-pain level 2- adverse reactions Main outcome is the level of pain reduction in three study groups at 15,30,45,60, and 90 minutes post drug administration. Adverse reaction incidence is compared between the three groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171106037280N2**
Registration date: **2018-02-21, 1396/12/02**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-21, 1396/12/02**
Update count: **0**

Registration date

2018-02-21, 1396/12/02

Registrant information

Name

hamed sotoude

Name of organization / entity

Kurdistan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 2027

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Recruitment status

Recruitment complete

Funding source

kurdistan university of medical sciences

Expected recruitment start date

2017-11-14, 1396/08/23

Expected recruitment end date

2018-04-05, 1397/01/16

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of ketamine and midazolam combination with ketamine and morphine for acute pain management at emergency department

Public title
The effect of ketamine and midazolam combination in comparison to ketamine and morphine for pain treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
moderate to severe pain acute pain at emergency department age 18-55
Exclusion criteria:
allergy to drugs pregnancy or lactation elevated intracerebral or intraocular pressure chronic pain
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **168**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization with allocating random numbers to patients and selecting the drug based on that number.
Blinding (investigator's opinion)
Double blinded
Blinding description
participant and investigator
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences
Street address
Iran, Sanandaj, Pasdaran St., Kurdistan University of Medical Sciences, Research Department
City
Sanandaj
Province
Kurdistan
Postal code
6618634683
Approval date
2016-12-26, 1395/10/06
Ethics committee reference number
IR.MUK.REC.1395.260

Health conditions studied

1

Description of health condition studied
acute pain in emergency department
ICD-10 code
G89.1
ICD-10 code description
Acute pain, not elsewhere classified

Primary outcomes

1

Description
pain intensity
Timepoint
15,30,60,90, and 120 min after drug adminidtrstion
Method of measurement
numeric rating scale (NRS)

Secondary outcomes

1

Description
changes in blood pressure
Timepoint
15,30,60,90, and 120 min after drug administration
Method of measurement
measurement of blood pressure by the sphygmomanometer

2

Description
nausea and vomiting
Timepoint
from beginning to the end (120 min after drug administration)
Method of measurement

observation

3

Description
dizziness
Timepoint
from beginning to the end (120 min after drug administration)
Method of measurement
history taking and asking from the patient

4

Description
behavioral change
Timepoint
from drug administration to 120 min afterwards
Method of measurement
observation

5

Description
delusion and hallucinations
Timepoint
from drug administration to 120 min afterwards
Method of measurement
observation and history taking

6

Description
changes in O2 saturation
Timepoint
from drug administration to 120 min afterwards
Method of measurement
continuous pulse oximetry

Intervention groups

1

Description
Intervention group 1: ketamine: ketamine 0.3 mg/kg IV infusion over 3-5 min (Rotexmedica drug company, ketamine hydrochloride), administered once at the beginning of the intervention.
Category
Treatment - Drugs

2

Description
Intervention group 2: ketamine-midazolam: ketamine 0.3mg/kg (Rotexmedica drug company, ketamine hydrochloride) and midazolam 0.03 mg/kg (aboureihan drug company, midazolam), infusion of the combination over 3 to 5 min, administered once at the beginning of the intervention.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar,Tohid, and Besat Hospital, emergency department
Full name of responsible person
hamed sotoude
Street address
pasdaran blvd, kurdistan university of medical sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
kurdistan university of medical sciences
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Hamed Sotoude
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sanandaj, pasdaran st., kowsar hospital, emergency department
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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
kurdistan 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
Kurdstan University of Medical Sciences
Full name of responsible person
Hamed Sotoude
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
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Sanandaj, Pasdaran st., Kowsar hospital, emergency department
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Person responsible for scientific inquiries

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assistant professor of emergency medicine
Latest degree
Specialist
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Person responsible for updating data

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Full name of responsible person
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Medical doctor
Other areas of specialty/work
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Web page address

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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The collected data about outcome will be disclosed
When the data will become available and for how long
the data will be published 1 year after the results.
To whom data/document is available
students and physicians and lecturers
Under which criteria data/document could be used
Data can be used under copyright rules.
From where data/document is obtainable
Data will be in access by sending an e-mail to H-sotude@razi.tums.ac.ir.
What processes are involved for a request to access data/document
The data would be reachable for whom with a qualified

letter from research department of their university or institute.

Comments