

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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, ketamine and midazolam, brain problems, weight 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

Email address

h-sotoude@razi.tums.ac.ir

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 administration

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 (aboureihaan 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 sotoode

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

Full name of responsible person

Hamed Sotoude

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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

Kurdistan 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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Hamed Sotoude

Position

assistant professor of emergency medicine

Latest degree

Specialist

Other areas of specialty/work

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Position

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Latest degree

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Other areas of specialty/work

Emergency Medicine

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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