

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Ketamine-Dexmedetomidine (Ketodex) versus Ketamine and ketofol for adult procedural sedation in Emergency Department

Protocol summary

Hemodynamic changes; Arterial O2 saturation changes;
Respiratory complications; Agitation

Study aim

Determining the consistency and effectiveness of Ketadex for Procedural Sedation and Analgesia (PSA) in comparing to ketamine and ketofol Determining the hemodynamic impacts and side effects of ketamine, Ketadex and Ketofol injection in Procedural Sedation and Analgesia (PSA) Determining the analgesic effectiveness of ketamine, Ketadex and Ketofol injection in Procedural Sedation and Analgesia (PSA) with Visual Analogue Scale (VAS) and Ramsay sedation score (RASS)

Design

This is a three arm parallel group (double blinded) randomized clinical trial study (third phase) with 145 cases. Patients are simple randomized with table of random numbers in 3 groups.

Settings and conduct

In this study we compare the effectiveness and side effects of Ketodex with Ketamine and Ketofol in adults PSA who refer to Alzahra and Kashani hospitals in Isfahan city. Drugs are preparing with scientist and labeled. Patients, scientist, manager and statistical analyst are blinded to randomization and treatment protocol.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with pain severity status of ASA I-III; Visual Analog Scale>4 Non-Inclusion Criteria: Addiction to drugs and analgesics; Use of analgesics in 24 hours ago; Underlying disease such as hypertension, liver and kidney disease); Pregnancy; Psychiatric disease such as psychosis; Severe verbal or hearing disability

Intervention groups

Intervention group 1: injection of 1 mg/kg diluted Ketamine in 20 ml normal saline over 4 minutes
Intervention group 2: injection of 0.5 mg/kg diluted Ketofol in 20 ml normal saline over 4 minutes
Intervention group 3: injection of 1 mg/kg diluted Ketamine and 0.7 microgram/kg Dexmedetomidine in 20 ml normal saline over 4 minutes

Main outcome variables

Pain severity score with Visual Analog Scale;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130108012072N13**

Registration date: **2022-08-30, 1401/06/08**

Registration timing: **prospective**

Last update: **2022-08-30, 1401/06/08**

Update count: **0**

Registration date

2022-08-30, 1401/06/08

Registrant information

Name

Mehrdad Esmailian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3629 3482

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Ketamine-Dexmedetomidine (Ketodex) versus Ketamine and ketofol for adult procedural sedation in Emergency Department

Public title
Ketodex Efficacy for adult procedural sedation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with pain severity status of Anesthesiology physical status I to III (ASA I-III), Visual Analog Scale>4
Exclusion criteria:
 Addiction to drugs and analgesics Use of analgesics in 24 hours ago Underlying disease such as hypertension, liver and kidney disease) Pregnancy Psychiatric disease such as psychosis Severe verbal or hearing disability Sensitivity to Ketamine, Ketofol and Ketodex

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with table of random numbers. In this study, based on predefined 3-digit number (001,002,003,...) randomization table, blindly choose one number, then upper and below numbers choose vertically as treatment code for each patient. After ending the the numbers, manager blindly choose another number again and apply the upper and below numbers for each patient. Every 3-digit number from 001 to 105, marked as one randomized treatment protocol (45 number for treatment protocol "A", 45 number for treatment protocol "B" and 45 number for treatment protocol "C"); study manager doesn't knowing about drug that use in each protocol. Chosen numbers must be lesser than sample size and greater numbers will be deleted. This protocol continued until all patients who meet inclusion criteria get a random number. Due to this method, patients stay on one treatment group, without knowing about treatment protocol.

Blinding (investigator's opinion)
Double blinded

Blinding description

Drugs are preparing with scientist and labeled (scientist is blinded to patient's treatment group and efficacy or complications of each groups). Patients are selected with randomized numeric table and don't aware about treatment protocol. Manager use treatment pathway base on patient randomization; blinded about drug that be used and record result and complications. Statistical analyst, analyses the study without knowing about patients group and give the results to researcher for conclusion.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezarjerib Ave., Azadi square, Isfahan, Iran
City
Isfahan
Province
Isfahan
Postal code
8175898595
Approval date
2022-08-27, 1401/06/05
Ethics committee reference number
IR.ARI.MUI.REC.1401.156

Health conditions studied

1

Description of health condition studied
Adult procedural sedation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain severity score with Visual Analog Scale
Timepoint
Study beginning, 30 minutes and 1 hour and 2 hours after treatment
Method of measurement
Visual Analog Scale

2

Description

Sedation level with Ramsay Sedation Score (RASS)

Timepoint

Study beginning, 30 minutes and 1 hour and 2 hours after treatment

Method of measurement

Ramsay Sedation Score (RASS)

Secondary outcomes

1

Description

Hemodynamic changes

Timepoint

Study beginning, 30 minutes and 1 hour and 2 hours after treatment

Method of measurement

Manometer; Heart rate; Pulseoximetry

2

Description

Agitation

Timepoint

Study beginning, 30 minutes and 1 hour and 2 hours after treatment

Method of measurement

Checklist

Intervention groups

1

Description

Intervention group 1: 1 mg/kg diluted Ketamine in 20 ml normal saline

Category

Treatment - Drugs

2

Description

Intervention group 2: 0.5 mg/kg diluted Ketofol in 20 ml normal saline

Category

Treatment - Drugs

3

Description

Intervention group 3: 1 mg/kg diluted Ketamine and 0.7 microgram/kg Dexmedetomidine in 20 ml normal saline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra General Hospital

Full name of responsible person

Mehrdad Esmailian

Street address

Alzahra general hospital, sofeh Blv

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2

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansoor Siavash

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Isfahan University of Medical Sciences, Hezarjerib Ave., Azadi square, Isfahan, Iran

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mehrdad Esmailian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Associate professor

Latest degree

Specialist

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Whole of data after coding

When the data will become available and for how long

Accessibility after 2023

To whom data/document is available

Everyone

Under which criteria data/document could be used

For seemingly studies data released to academic chairman's

From where data/document is obtainable

Isfahan University of Medical Sciences

What processes are involved for a request to access

data/document

Emailing to m_esmailian@med.mui.ac.ir

Comments