

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Comparison of Post-Operative Recovery Agitation after Three Analgesic Methods: Ketadex; Ketofol and Ketamine administration in the Emergency Departments in Iran

Protocol summary

Study aim

Ketamine-related agitation is one of the most common post-analgesic complications in both adult and children. In the emergency department, managing this problem is important and remains to be a remarkable challenge. This study will assess the effect of dexmedetomidine in combination of ketamine on incidence of EA comparing to ketofol and ketamine as one sedative drug.

Design

three groups, parallel groups (ketodex, ketofol, ketamine), double-blinded, phase III, 31 patients in each group,

Settings and conduct

The data recruiting physician and the patient will not know what the drug the nurse has used for analgesia induction or the group of the patient.

Participants/Inclusion and exclusion criteria

Female/Male age over 3 years American Society of Anesthesiology physical status I to III (ASA I-III) VAS score of pain equal to or higher than 4 need for painful procedures in Emergency Department

Intervention groups

Depending on their random group, patients will receive slowly intravenous Ketadex (0.7 µg.kg-1 dexmedetomidine and 1 mg/kg ketamine in one syringe) over 4 minutes or ketofol (0.5 mg/kg from each of ketamine and propofol) or 1 mg/kg ketamine alone, both intravenously over 2 minutes. Additional sedative rescue doses will be provided as 0.25 mg/kg ketamine every 2 minutes, in all patients if needed.

Main outcome variables

Patient's agitation score and sedation consistency, assessed by RASS score (e.g. Richmond Agitation Sedation Scale); Heart Rate, oxygen saturation, systolic and diastolic blood pressure will be continuously monitored before sedation until full recovery time and recorded every 5 minutes for 2 hours.

General information

Reason for update

Acronym

Ketodex (=Ketamine and Dexmedetomidine) - Ketofol (=Ketamine and Propofol).

IRCT registration information

IRCT registration number: **IRCT20190422043340N1**

Registration date: **2019-05-14, 1398/02/24**

Registration timing: **prospective**

Last update: **2019-05-14, 1398/02/24**

Update count: **0**

Registration date

2019-05-14, 1398/02/24

Registrant information

Name

Soheila Kouhestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3223 8055

Email address

dr.kouhestani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-07-11, 1398/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Post-Operative Recovery Agitation after Three Analgesic Methods: Ketadex; Ketofol and Ketamine administration in the Emergency Departments in Iran

Public title

Recovery Agitation after Administration of Ketadex, Ketofol and Ketamine

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Female/Male age over 3 years American Society of Anesthesiology physical status I to III (ASA I-III) VAS score of pain equal to or higher than 4 need for painful procedures in Emergency Department such as: Reduction of extremity fracture or dislocation and repair of skin lacerations

Exclusion criteria:

Patients showing serious adverse events of the drugs

Age

From **3 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using Google™ Random Number Generator we will obtain 90 random numbers among 1, 2 and 3, print them out on a piece of paper, put them each into a closed envelope, and after each patient fulfills the inclusion criteria, the patient will be taken to the operation room of the emergency departments with an envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The nurse will use an analgesia induction drug based on the number in the envelope, after prepping the patient. Then, the nurse will discard the envelope, the drug, and the syringe and will call the physician in for continuing the procedure. The physician and the patient will not know what the drug the nurse has used or the group of the patient.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Isfahan University of Medical Sciences and Health Services

Street address

Research Ethics Committee, Faculty of Medicine, Isfahan University of Medical Sciences, Hezar Jarib St.

City

Isfahan

Province

Isfahan

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8174673461

Approval date

2017-04-12, 1396/01/23

Ethics committee reference number

IR.MUI.REC.1396.3.356

Health conditions studied**1****Description of health condition studied**

"recovery agitation"

ICD-10 code

R45.1

ICD-10 code description

Restlessness and agitation

Primary outcomes**1****Description**

Patient's agitation and sedation consistency, assessed by RASS score (e.g. Richmond Agitation Sedation Scale)

Timepoint

Patient's agitation score and sedation consistency will be assessed by RASS score (Richmond Agitation Sedation Scale) within two minutes from induction of sedation and during recovery until 2 hours.

Method of measurement

RASS score (Richmond Agitation Sedation Scale)

Secondary outcomes**1****Description**

Heart Rate, oxygen saturation, systolic and diastolic blood pressure

Timepoint

Every five minutes from the start point of analgesia induction until 2 two hours after full recovery.

Method of measurement

sphygmomanometer for blood pressure, pulse oximeter for heart rate and blood oxygen saturation

Intervention groups

1

Description

Intervention group: Ketodex

Category

Prevention

2

Description

Intervention group: Ketofol

Category

Prevention

3

Description

Control group: Ketamine

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Soheila Kouhestani

Street address

Soffeh Boulevard

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8174675731

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+98 31 3620 2020

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r_azizkhani@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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

60

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

Soheila Kouhestani

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data on agitation score and hemodynamic indices of the patients who are consciously informed and consented about the study and are included in the study will be shared.

When the data will become available and for how long

The data will be available from six months after the end of the patient recruitment and will be published as an article and will always be available.

To whom data/document is available

Everyone.

Under which criteria data/document could be used

Everyone can use our data only after requesting and granting our permission.

From where data/document is obtainable

Through email towards the person who has requested to have the data.

What processes are involved for a request to access data/document

Obtaining our email addresses and requesting throughout an email.

Comments