Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 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
Isfehan

Postal code
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
sphygmomonometer for blood pressure, pulse oxymeter 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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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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Isfahan University Of Medical Sciences, Hezar Jarib St.
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Phone
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Email
dean@mui.ac.ir
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
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Emergency Medicine
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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