Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the Effectiveness of intravenous Ketamine and Precedex(dexmedetomidine) in the Relaxation of Pediatric Patients in Emergency Department

Protocol summary

Study aim
Comparison the Effectiveness of intravenous Ketamine and Precedex in the Relaxation of Pediatric Patients referred to Emergency Department

Design
Clinical trial of two groups with blind and randomized parallel form

Settings and conduct
This study was performed on children referred to emergency department of Imam Reza Hospital and Hasheminejad Hospital in Mashhad.In the group (A) 1.5-2 mg / kg, ketamine is injected intravenously once a day. In group (B), 2µg / kg Precedex drug will be injected within 10 minutes as the initial dose and then 2µg / kg Precedex will be injected intravenously as a second dose. Injections will be done by the investigator.Information about each patient, including age, sex, kind of drug that used for sedation, time duration to being sedate and recovery time using the Ramsy scale, will be recorded in the information form .The vital signs include BP, PR, RR, O2Sat, and the Ramsy scale of the patients will be measured at onset, 10 minutes after the injection, before the beginning of repair, and after the end of repairing the injury. patients and assessor will be blinded.

Participants/Inclusion and exclusion criteria
patients with the condition of needing a sedation to repair the injury and the age group of 2 to 12 years will be included in the study.Patients with unstable vital signs, patients with uncontrolled bleeding, deep tissue damage such as tendons and main vessels, respiratory infections, drug allergy , and patients with a history using of analgesic and sedative drugs are excluded from Study.

Intervention groups
n the group (A) 1.5-2 mg / kg, ketamine is injected intravenously once a day. In group (B), 2µg / kg Precedix drug will be injected within 10 minutes intravenously as the initial dose and then 2µg / kg Precedix will be injected intravenously.

Main outcome variables
time duration to being sedate and recovery time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161226031577N2**
Registration date: **2018-07-09, 1397/04/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-09, 1397/04/18**
Update count: **0**

Registration date
2018-07-09, 1397/04/18

Registrant information

Name
behrang rezvani kakhki

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 51 3761 4622

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rezvanikb@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effectiveness of intravenous Ketamine and Precedex(dexmedetomidine) in the Relaxation of Pediatric Patients in Emergency Department

Public title

The effect of intravenous precedex on pediatric sedation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with the condition of needing a sedation to repair the injury Age group 2-12 years

Exclusion criteria:

Patients with unstable vital signs Patients with uncontrolled bleeding Deep tissues damage, such as the tendons and main vessels Patients with respiratory infections Drug susceptibility to drugs used Patients with a history of using analgesic and sedative drugs

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization Patients will be divided into two groups, A and B, by random number table. (The allocation of numbers to groups and directions is already determined,Put the pen on the table with blind eyes, Select the starting point)

Blinding (investigator's opinion)

Double blinded

Blinding description

The purpose of the study is explained to the patient's parents and their consent to participate in the study is taken.Assigning person and patient will not be informed of the assignment.The outcome evaluator will not be aware of how the medicine will be allocated to patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences ethical committee

Street address

Ghoreyshi Building, Daneshgah Strees, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9184938764

Approval date

2018-01-28, 1396/11/08

Ethics committee reference number

IR.MUMS.fm.REC.1396.534

Health conditions studied

1

Description of health condition studied

Patients requiring sedation to repair the injury of the hand

ICD-10 code

S61.41

ICD-10 code description

Laceration , hand

2

Description of health condition studied

Patients requiring sedation to repair the injury of the foot

ICD-10 code

S91.31

ICD-10 code description

Laceration, foot

Primary outcomes

1

Description

duration time to sedate and recovery time

Timepoint

At the initial time of entry, 10 minutes after the injection of the drug, before the repair is restored and after the injury is repaired

Method of measurement

Ramsy scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: percedex drug. Pridecox drug will be injected 2µg / kg intravenously as the initial dosea within 10 minutes and followed by 2µg / kg intravenously Precedix as the second dose.
Category
Treatment - Drugs

2

Description
Control group: Ketamin drug.1.5-2 mg / kg ketamine is injected intravenously once a day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hasheminejad and Imam Reza hospitals
Full name of responsible person
Behrang rezvani Kakhki
Street address
Imam Reza square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Affair Of Mashhad University Of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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Grant name
Comparison the Effectiveness of intravenous Ketamine and Precedex(dexmedetomidine) in the Relaxation of Pediatric Patients in Emergency Department
Grant code / Reference number
10433
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Affair Of Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Behrang Rezvani Kakhki
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there is no more information

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

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

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

Clinical Study Report
Undecided - It is not yet known if there will be 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