

# 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

in 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)

##### Phone

+98 51 3761 4622

##### Email address

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 Streets, 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. Pridex drug will be injected 2µg / kg intravenously as the initial dose within 10 minutes and followed by 2µg / kg intravenously Pridex 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

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9184938764

#### Phone

+98 51 3804 9039

#### Email

rezvanikb@mums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Research Affair Of Mashhad University Of Medical Sciences

#### Full name of responsible person

Mohsen Tafaghodi

#### Street address

Mellat Square

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

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#### Phone

+98 51 3800 2104

#### Email

Rezvanikb@mums.ac.ir

### Grant name

Comparison the Effectiveness of intravenous Ketamine and Pridex(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

#### Street address

Shahid Hasheminezhad Hospital, Andishe Street, Tolab boulevard, Mashhad, Iran

#### City

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#### Postal code

12345

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#### Email

Rezvanikb@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Dr. Behrang Rezvani Kakhki

#### Position

Assistant Professor of Emergency Medicine

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

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**Web page address**

**Person responsible for updating data**

**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

**Street address**

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**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

12345

**Phone**

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**Fax**

+98 51 3852 5312

**Email**

Rezvanikb@mums.ac.ir

**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