

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparing intramuscular and intranasal Ketamin in pain reduction of pediatrics between 2 and 15 years during procedural sedation in emergency department

Protocol summary

Summary

Object: Comparing the effect of intranasal Ketamin with intramuscular Ketamin in decreasing the pain in pediatric patients. Methods and Material: The above study is a double blind and randomized clinical trial which will be accomplished on 60 children aging 2 to 15 years, with the same physical conditions and same circumstances admitted in Tehran Hazrate Rasoul Hospital. The patients admitted according to the criterion of the study will be randomly divided in one of two groups of the study; Interventions: It means 30 patients will be considered for each group. For group one, one to two milligrams per kilogram of intramuscular Ketamin and for the second group one to two milligrams per kilogram of intranasal Ketamin will be administered. The children will be evaluated before, during and after drug administration using pain evaluation scales for children and also the level of their satisfaction and the results will be documented. Inclusion Criteria: Necessity to perform different types of procedures including repair of lacerations in different sizes and in every region of body and also types of reductions in emergency department; Level of consciousness more than 15 in GCS format; Age between 2 and 15; Not suffering of any mental disorders; Consent of the patient for the procedures. Exclusion Criteria: Any past history of surgery on trachea or tracheal stenosis; Active lung infection; Intake of large amount of food during three hours before procedure; Cardiovascular diseases including angina and heart failure and hypertension; Trauma or head injury resulting in lowering level of consciousness or vomiting; Mass in CNS or hydrocephalus; Not well controlled seizure ; Glaucoma or Acute globe injury; Psychosis and Porphyria and Thyroid Disease and treatment with drugs of thyroid disease; Cardiac complications due to Ketamin administration; Not having consent of parents and guardians or the patient himself. Primary Outcome

Value: evaluation of pain in different intervals: before, during and after drug administration using pediatric pain scales.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052417825N1**

Registration date: **2014-07-06, 1393/04/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-06, 1393/04/15

Registrant information

Name

Elham Sheikh aboumasoudi

Name of organization / entity

Emergency medicine

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Tehran University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing intramuscular and intranasal Ketamin in pain reduction of pediatrics between 2 and 15 years during procedural sedation in emergency department

Public title

Comparing intramuscular and intranasal Ketamin in procedural sedation of pediatrics between 2 and 15 years

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Necessity to perform different types of procedures including repair of lacerations in different sizes and in every region of body and also types of reductions in emergency department; Level of consciousness more than 15 in GCS format; Age between 2 and 15; Not suffering of any mental disorders; Consent of the patient for the procedures. Exclusion Criteria: Any past history of surgery on trachea or tracheal stenosis; Active lung infection; Intake of large amount of food during three hours before procedure; Cardiovascular diseases including angina and heart failure and hypertension; Trauma or head injury resulting in lowering level of consciousness or vomiting; Mass in CNS or hydrocephalus; Not well controlled seizure ; Glaucoma or Acute globe injury; Psychosis and Porphiria and Thyroid Disease and treatment with drugs of thyroid disease; Cardiac complications due to Ketamin administration; Not having consent of parents and guardians or the patient himself.

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Ghods street- Keshavarz blvd- Tehran

City

Tehran

Postal code**Approval date**

2012-10-28, 1391/08/07

Ethics committee reference number

1815/ 130 /91/3

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

Extremity Trauma

ICD-10 code

XIII

ICD-10 code description

Musculoskeletal System and Connective Tissue Diseases

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

Pain Severity

Timepoint

Before, during and after drug administration

Method of measurement

Administration of Visual Analogue Scale and asking the patient to determine the picture representative of pain severity

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

changes in Vital Signs and Side effects

Timepoint

Before, during and after drug administration

Method of measurement

According to history and physical examination

Intervention groups

1

Description

Intervention Group: Nasal spray of 1-2 mg/kg of Ketamin

Category

Treatment - Drugs

2

Description

Control Group: Intramuscular injection of 1-2 mg/kg Ketamin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency Department of Hazrate Rasool (S) Educational-Therapeutic Centre

Full name of responsible person

Saieed Abbasi, Medical Doctor

Street address

Emergency Department, Hazrate Rasool Hospital, Niyayesh street, Sattarkhan, Tehran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh, Medical Doctor

Street address

Tehran University of Medical Sciences, Enghelab St.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Deputy of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Saeed Abbasi, Medical Doctor

Position

Assistant Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty