

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Efficacy and safety of oral low dose ketamine for pediatric Intravenous cannulation

#### Protocol summary

##### Summary

Purpose of study: Evaluating the efficacy and safety of oral low dose ketamine for pediatric Intravenous cannulation. Design: prospective randomized double blind placebo controlled, Single-center, Phase II trial  
Inclusion criteria: children aged 3 to 6 years with no baseline pain who are peroral. Exclusion criteria: having any medical condition in which procedure is emergent and there is no 20-30 minutes chance to take analgesic; having any contraindication for prescribing ketamine (included but not limited to high blood pressure; high intracranial pressure; high intraocular pressure; Heart failure; Thyroid diseases; Respiratory system instability); the history of taking ketamine by patient in the last 24 hour in this center (in this study); 4. American Society of Anesthesiologists class  $\geq$  III; abnormal neurological exam; lack of parental consent; having any condition that makes evaluating pain difficult; Glasgow Coma Scale less than 15. Sample size: 70 (35 in each group). Intervention: in intervention group, ketamine (Intravenous formulation) mixed with orange juice with dose of 3 mg/kg given orally as a single dose. patient in control group take only orange juice. After 20 - 30 minutes intravenous placement is done and the amount of pain in the two groups is measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201504251764N3**  
Registration date: **2015-07-06, 1394/04/15**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-07-06, 1394/04/15

#### Registrant information

##### Name

Toktam Faghihi

##### Name of organization / entity

Tehran university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6695 4709

##### Email address

tfaghihi@razi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2014-03-20, 1392/12/29

#### Expected recruitment end date

2016-03-19, 1394/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Efficacy and safety of oral low dose ketamine for pediatric Intravenous cannulation

#### Public title

Effect of Ketamine for pediatrics pain

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: children with no pain at baseline will enter the study! also children take part in the study who are able to take the drug orally. Exclusion criteria: having any medical condition in which procedure is emergent and there is no 20-30 minutes chance to take analgesic;

having any contraindication for prescribing ketamine (included but not limited to high blood pressure; high intracranial pressure; high intraocular pressure; Heart failure; Thyroid diseases; Respiratory system instability); the history of taking ketamine by patient in the last 24 hour in this center (in this study); 4. American Society of Anesthesiologists class  $\geq$  III; abnormal neurological exam; lack of parental consent; having any condition that makes evaluating pain difficult; Glasgow Coma Scale less than 15.

#### Age

From **3 years** old to **6 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **70**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

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

Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.

##### City

Tehran

##### Postal code

141556451

#### Approval date

2015-01-26, 1393/11/06

#### Ethics committee reference number

9111358004-137896

## Health conditions studied

### 1

#### Description of health condition studied

pain during Intravenous placement in pediatrics

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

pain while Intravenous placement in pediatrics

#### Timepoint

30 minutes after taking oral Ketamine

#### Method of measurement

Measurement of pain in children ; pain score(Children's Hospital of Eastern Ontario Pain Scale, Visual Analog Scale)

### 2

#### Description

Cooperation during catheter insertion

#### Timepoint

30 minutes after taking the oral ketamine

#### Method of measurement

I.V Sedation Scale

## Secondary outcomes

### 1

#### Description

Potential side effects due to use of oral ketamine

#### Timepoint

first 1 hour and 24 hours after taking of oral ketamine

#### Method of measurement

Checklist of side effects of ketamine

## Intervention groups

### 1

#### Description

After obtaining consent from the parents of patients , patients are classified in two groups of intervention and control by permuted block randomization . Then for each group a questionnaire including demographic informations , age, gender, weight, chief complaint, ASA class, primary diagnosis, receiving concomitant medications, location of Intravenous placement and other required information are recorded. In the intervention group ketamine mixed in orange juice with dose of 3 mg/kg is given to patients orally one dose. after 20- 30 minutes Intravenous placement is done and the pain of patients is measured with desired scales during the procedure.

#### Category

Treatment - Drugs

### 2

#### Description

After obtaining consent from the parents of patients ,

patients are classified in two groups of intervention and control by permuted block randomization . then for each group a questionnaire including demographic informations , age, gender, weight, chief complaint, ASA class, primary diagnosis, Receiving concomitant medications, location of Intravenous placement, duration of procedure, final diagnosis and other required information are recorded. in the control group,patients take only orange juice. after20- 30 minutes iv placement is done and the pain of patients is measured with desired scales during the procedure.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Children's Hospital Medical Center

**Full name of responsible person**

Mahdi Bagheri(Resident of Clinical Pharmacy)

**Street address**

No. 62, Doctor Mohammad Gharib Street, Keshavarz Blvd, next to Imam Khomeini hospital,Tehran, Children's Medical Center

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research,Tehran University of Medical Sciences

**Full name of responsible person**

Masoud Yunesian

**Street address**

Vice chancellor for research,Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research,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**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mahdi Bagheri

**Position**

Resident of Clinical Pharmacy

**Other areas of specialty/work****Street address**

Faculty of Pharmacy of Tehran University of Medical Sciences, 16 Azar Street, Enghelab Square, Tehran

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Web page address**

**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*