

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Effect of ketamine intranasal with placebo in ease of access to peripheral veins and reduce child pain

#### Protocol summary

##### Study aim

The aim of the study is to determine the effect of ketamine intranasal with placebo in ease of access to peripheral veins and reduce child pain

##### Design

The design of the study is a randomized clinical trial. The randomization method is blocked. The sample size for each study group is 40.

##### Settings and conduct

The main aim of the study is the success venipuncture of the pediatric ward of children referred to the Emergency Department of Ali Asghar Hospital, Iran University of Medical Sciences in 2018. participants and physicians assess clinical conditions of patients will be blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 6 months to 6 years in an emergency needing to venipuncture. Exclusion criteria: Unwell children; Intense dehydration; having a history of allergy to ketamine; seizure; having brain lesions; increased intracranial pressure.

##### Intervention groups

Before doing venipuncture, ketamine will be given intranasal with a dose of 4 miligram per Kilograms body weight and According to the half-life and the maximum effect time of the drug will be taken venipuncture 5 minutes later.

##### Main outcome variables

Success in venipuncture; duration of start venipuncture until the end; pain patient.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120613010017N7**

Registration date: **2018-06-17, 1397/03/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-06-17, 1397/03/27**

Update count: **0**

##### Registration date

2018-06-17, 1397/03/27

##### Registrant information

###### Name

Hamed Basir Ghafouri

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6653 9233

###### Email address

h-basirghafouri@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-24, 1397/02/04

##### Expected recruitment end date

2018-11-25, 1397/09/04

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of ketamine intranasal with placebo in ease of access to peripheral veins and reduce child pain

##### Public title

Effect of ketamine intranasal in ease of access to peripheral veins

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Children aged 6 months to 6 years in an emergency needing to venipuncture

**Exclusion criteria:**

Unwell children Intense Dehydration Having a history of allergy to ketamine Seizure Having brain lesions Increased intracranial pressure

**Age**

From **6 months** old to **6 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants in the study will be assigned to two groups using a block randomization method.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants in the study will be blinded of the type of received intervention. Physicians assessing the clinical conditions of participants will be blinded of the type of intervention received by patients.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Hemmat Highway, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2018-06-12, 1397/03/22

**Ethics committee reference number**

IR.IUMS.FMD.REC.1396.9511307006

**Health conditions studied**

**1**

**Description of health condition studied**

Easy venipuncture in all children that venipuncture is needed in the process of treatment

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Success in venipuncture

**Timepoint**

Count the insert needle

**Method of measurement**

Count

**2**

**Description**

Duration in successful venipuncture

**Timepoint**

Duration from start to end of successful venipuncture

**Method of measurement**

Observe

**Secondary outcomes**

**1**

**Description**

Patient pain

**Timepoint**

End of venipuncture

**Method of measurement**

Using Visual Analogue Scale for pain measurement

**Intervention groups**

**1**

**Description**

Intervention group: Before doing venipuncture, intranasal ketamine will be given with a dose of 4 miligram per Kilograms body weight and according to the half-life and the maximum effect time of the drug will be taken venipuncture 5 minutes later.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Intranasal Normal Saline will be prescribed in the form of spray before venipuncture doing. After 5 minutes venipuncture will be taken.

**Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Rasoul Akram hospital

**Full name of responsible person**

Hamed Basir Ghafouri

**Street address**

Rasoul Akram hospital, Niyayesh St, Sattar Khan St.

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۵۶۱۳۱۳۱

**Phone**

+98 21 6653 9233

**Email**

Basirghafoori.h@iums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Kazem Malakouti

**Street address**

Rasoul Akram hospital, Niyayesh St, Sattar Khan St.

**City**

Tehran

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Hamed Basir Ghafouri

**Position**

Assistance professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Rasoul Akram hospital, Niyayesh St, Sattar Khan St.

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## Person responsible for scientific inquiries

### Contact

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Iran University of Medical Sciences

**Full name of responsible person**

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## Person responsible for updating data

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

**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