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 miligeram 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 unitl 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 miligeram 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.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Kazem Malakouti
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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
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Person responsible for scientific inquiries

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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