

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison of the effect of local anesthesia induced by intradermal injection of ketamine with lidocaine in intravenous venipuncture

#### Protocol summary

##### Study aim

Comparing the effect of local anesthesia caused by intradermal injection of ketamine with lidocaine in venous venipuncture in the emergency department of Boali Hospital

##### Design

A clinical trial with a control group, with parallel groups, double-blind, phase 2 on 246 patients.

##### Settings and conduct

In group (a), 0.2 ml of buffered lidocaine, is injected intradermally. In group (b), we inject 0.2 ml of 1 mg ketamine solution intradermally, and in group (c) we inject 0.2 ml of normal saline. Venipuncture will be done After two to three minutes. The method of blinding is as follows: ketamine, lidocaine, and normal saline in 100 ml vials. The same will be poured and one of the letters a, b, c will be written on each one, and the patients will be randomly divided into three groups and receive a coded vial. Visual analog scale use for assessing patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include the age range of 18-60 years, alertness and ability to communicate verbally, provide written consent and the need to take a venous vein under the supervision of a physician. Patients with unwillingness to continue to participate in the study, history of allergies to local anesthetics (lidocaine / prilocaine, tetracaine and benzocaine), opioid addiction, severe analgesia addiction, peripheral vascular diseases, sensory disorders such as diabetic neuropathy, cognitive disorders, And a history of needle phobias and panic attacks are excluded.

##### Intervention groups

246 people in three groups of 82 people are divided into 3 groups receiving buffered lidocaine, ketamine and placebo (normal saline).

##### Main outcome variables

the amount of pain caused by venipuncture, heart rate (dependent variables);

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200707048047N2**

Registration date: **2022-09-07, 1401/06/16**

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

Last update: **2022-09-07, 1401/06/16**

Update count: **0**

##### Registration date

2022-09-07, 1401/06/16

##### Registrant information

##### Name

Masoumeh Moallem

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2611 6628

##### Email address

masoumehmoallem@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-28, 1401/04/07

##### Expected recruitment end date

2022-10-29, 1401/08/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of local anesthesia induced by intradermal injection of ketamine with lidocaine in intravenous venipuncture

#### Public title

Comparison of the effect of local anesthesia induced by intradermal injection of ketamine with lidocaine in intravenous venipuncture

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

عدم تمایل بیمار به ادامه مشارکت در مطالعه سابقه حساسیت به بی حس کننده های موضعی ( لیدوکائین/پرپیلوکائین تتراکائین و بنزوکائین) اعتیاد به اپیوئیدها اعتیاد به ضد دردهای قوی مناسب نبودن عروق ناحیه آنته کوبیتال جهت رگ گیری بیماری های عروق محیطی اختلالات حسی مثل نوروپاتی دیابتی اختلالات شناختی سابقه فوبیا سوزن و حملات پانیک

##### Exclusion criteria:

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **246**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Blinding is done in such a way that ketamine, lidocaine and normal saline are poured into similar 100 ml vials and each of the letters a, b, c is written and patients are randomly divided into three groups. Depending on whether they were in groups 1,2 or 3, they will receive a coded vial, and the researcher prescribing the drug is not aware of the type of drug, and later in the statistical analysis it will be determined which drug in each group Patients Nurses and data collectors do not know the type of substance used for each patient.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

کمیته اخلاق در پژوهش دانشکده پزشکی- دانشگاه علوم پزشکی آزاد اسلامی تهران

##### Street address

khaghani

##### City

Tehran

##### Province

Tehran

##### Postal code

1916893813

#### Approval date

2022-03-12, 1400/12/21

#### Ethics committee reference number

IR.IAU.TMU.REC.1401.022

## Health conditions studied

### 1

#### Description of health condition studied

venipuncture

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The amount of pain caused by venipuncture

#### Timepoint

Three minutes after the intervention

#### Method of measurement

Visual analog scale (VAS). (0-3) mild pain, (4-6) moderate pain and (10-7) severe pain.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first intervention procedure: 0.2 ml of buffered lidocaine, which is obtained by adding two ml of 7.5% bicarbonate to twenty-two ml of 1% lidocaine, is injected intradermally. The second intervention group: 0.2 ml of 1 mg ketamine solution will be injected intradermally. After two to three minutes, the target area will be disinfected and the vein will be removed by professional nurses who did not know about the study. All cases of venipuncture are performed using venous catheter gage 21 in the area of the middle cubital vein. Ketamine is a cyclohexanone derivative used to induce anesthesia. Its mechanism of

action is not well understood, but ketamine can block NMDA (N-Methyl-D-Aspartate) receptors and may interact with sigma receptors. Lidocaine is a local anesthetic and cardiac depressant that is known as Antiarrhythmic agent is used. Its action is more intense and its effects are longer than the effects of procaine, but its duration of action is shorter than that of bupivacaine or prilocaine. Three vials of lidocaine 2% (50 ml) are used at the unit price of 1471000 Rial in Shahid Ghazi pharmaceutical company, built inside. Ketamine vials of 50 mg/ml (10 ml) are three units at the unit price of 3500000 in the pharmaceutical company. Internally made elixir is used. 246 pink venous catheter are used at the unit price of 33,000 Rial made by Polymed. 246 sets of serums are used at a unit price of 55,000 Rial made by Polymed.

#### Category

Treatment - Drugs

## 2

#### Description

Control group: Control group: 0.2 ml of normal saline will be injected intradermally and after two to three minutes the target area will be disinfected and the vein will be removed by professional nurses who were not aware of the study. All cases of venipuncture are performed using venous catheter gage 21 in the area of the middle cubital vein. Injectable normal saline is used in four units at the price of 184,800 Rial, the Iranian injectable and medicinal products.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Boali hospital Tehran

##### Full name of responsible person

Masoumeh moallem

##### Street address

Boali hospital, Damavand st, Imam Hosein sq, Tehran

##### City

Tehran

##### Province

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##### Postal code

1711734365

##### Phone

+98 21 3334 8036

##### Email

masoumehmoallem@gmail.com

##### Web page address

<http://bouali.iautmu.ac.ir/fa>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Alireza Khoshdel

##### Street address

khaghani

##### City

Tehran

##### Province

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##### Postal code

1916893813

##### Phone

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##### Email

pezeshkitehran.8@gmail.com

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Islamic Azad University

#### Proportion provided by this source

20

#### 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

Islamic Azad University

##### Full name of responsible person

masoumeh moallem

##### Position

assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Emergency Medicine

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Islamic Azad University

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Position**

assistant professor

**Latest degree**

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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