Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Double-blinded placebo-control study of intranasal ketamin effects and complications in digital nerve block in traumatic hand injuries

Protocol summary

Summary

This is a double-blinded placebo-controlled interventional study that will performed in emergency department of a teaching hospital. All patients with traumatic hand fingers injuries who needed digital nerve block and older than 15 years will enter the study. Exclusion criteria are pregnancy, allergy to Ketamine or Lidocaine, communication problem and serious cardiovascular problems. Initial pain will be evaluated by Visual Analogue Scale. Patients will be randomly divided to two groups; Intervention group that receives 1cc of Ketamine and control group that receives 1cc of distilled water. The fluid will drop on one of nostrils of patients. 5 minutes later pain will be evaluated again and digital nerve block will be done as an standard and routine manner. The procedure will be performed after 5 minutes. Pain of block and procedure will be evaluated by VAS. Blood pressure and pulse rate will be measured before and right after 30 min after the procedure. Patients will be observed for half an hour for complications of Ketamine such as hallucination, nausea, vomiting, cough and other complications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206289162N3**
Registration date: **2013-04-21, 1392/02/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-04-21, 1392/02/01

Registrant information

Name

Amir Nejati

Name of organization / entity

Tehran University of Medical Sciences, Imam Khomeini Hospital

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Recruitment status

Recruitment complete

Funding source

The project presented as a final thesis of one of the residents of emergency medicine educational group at Tehran University of Medical Sciences

Expected recruitment start date

2011-01-01, 1389/10/11

Expected recruitment end date

2011-10-30, 1390/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double-blinded placebo-control study of intranasal ketamin effects and complications in digital nerve block in traumatic hand injuries

Public title

The effect of intranasal Ketamine on digital nerve block pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Hand fingers trauma needed to digital nerve block for procedures; patients who signed the

consent form Exclusion criteria: Age under 15; Can not communicate because of mental retardation; language barriers, loss of consciousness, intoxication or other causes; Pregnancy; Hemodynamic instability (systolic BP less than 90 or more than 180 mmHg); Chronic opium user or use any of sedative-analgesic in last 12 hours; Known reactive or anatomic airway diseases; Decompensated heart failure or acute coronary syndrome (based on History and physical exam OR documentations) ; Known allergy to Ketamine or Lidocaine.

Age
From **15 years** old to **100 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **0**

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 research, Tehran University of Medical Sciences

Street address
6th floor, Central building, Qods Avenue, Keshavarz blvd

City
Tehran

Postal code

Approval date
2012-11-10, 1391/08/20

Ethics committee reference number
1935/130/D/91

Health conditions studied

1

Description of health condition studied
Local Anesthesia of Digital Nerve

ICD-10 code
Y48.3

ICD-10 code description
Local anaesthetics

Primary outcomes

1

Description
Pain of injured finger

Timepoint
entrance, after instillation of drug or placebo (pre-procedural pain), after completion of procedure (post-procedure pain)

Method of measurement
Numeric Rating Scale (NRS) 10 part

2

Description
Complication of control or placebo drug

Timepoint
continouesly from initial instillation of drug until 30 min after procedure

Method of measurement
Ketamine complication such as Hallucination, Nausea, vomiting, hypertension, agitation and seizure

Secondary outcomes

1

Description
Heart Rate

Timepoint
Before instilation and 30 min after that

Method of measurement
By pulse-oxymeter or Cardiac monitor

2

Description
Systolic BP

Timepoint
Before instilation and 30 min after that

Method of measurement
Sphygmomanometer

3

Description
Arterial O2 Saturation

Timepoint
Before instilation and 30 min after that

Method of measurement
By pulse-oxymeter

4

Description

Procedure complication

Timepoint

Begining of procedure until 30 min after that

Method of measurement

Hematoma, Bleeding, Ischemia, ...

Intervention groups

1

Description

Control group: 2 cc identical syringes contain 1cc Ketamine(=50mg) or 1cc distilled water prepared out of emergency department in blocks of 12. In control group 1 cc of distilled water will drop in one of nostrils of patients and ask them to hold their breath as could as possible and do not cough. All patients will observe for another 30 minutes for probable complications.

Category

Placebo

2

Description

Intervention group: 2 cc identical syringes contain 1cc Ketamine(=50mg) or 1cc distilled water prepared out of emergency department in blocks of 12. In intervention group 1 cc of Ketamine (=50 mg) will drop in one of nostrils of patients and ask them to hold their breath as could as possible and do not cough. All patients will observe for another 30 minutes for probable complications.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency department, Imam khomeini complex medicalcenter

Full name of responsible person

Amir Nejati M.D.

Street address

Emergency Department, Imam Khomeini hospital, Bagherkhan street, Tohid square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akhondzadeh, Deputy of research, Medical School

Street address

Medical School, Poorsina Avenue, 16 Azar, Keshavarz Blvd, Tehran

City

Tehran

Grant name

Grant code / Reference number

Student thesis grant

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

Yes

Title of funding source

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

Amir Nejati M.D.

Position

Assistant Professor, Faculty of educational group of Emergency Medicine

Other areas of specialty/work

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Position

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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