

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of Analgesia of Fentanyl with Ketamine during Injection of Propofol

Protocol summary

Summary

After obtaining written informed consent from eligible patients, and getting an approval from Ethics committee of Ahvaz Jundishapur University of Medical Sciences, a double-blind prospective, randomized study will be done among patients with elective surgery. Inclusion criteria: - The patient's satisfaction - Age between 20 and 60 years old. Exclusion criteria: - History of substance abuse; hypnotics or narcotics throughout 24 hours before the surgery - History of drug abuse, or alcohol- dependency - Contraindication of Propofol or Ketamine - High Intracranial Pressure Patients will be randomly allocated into three groups according to table of random numbers. Groups "one", "two", and "three" will receive normal saline 0.9%, 0.1 mg/kg of intravenous (IV) ketamine, and 1 mcg/kg of Intravenous Fentanyl, respectively. After 45 seconds, 1.5 mg/kg of propofol will be injected (at speed of 1 ml/s) and every 5 seconds, paying attention to the patient's face, using the method of Verbal Rating Scale (VRS) grading 0 to 3 {0-No; 1-Slight pain or discomfort; 2-Moderate pain; 3-Severe pain (changing the face or hand pulling back)}. Then, the patient will be asked about the pain during injection. Subsequently, the rest of propofol infusion will be injected and after reduced level of consciousness, other steps of anesthesia will be done. Then grading of pain during recovery, 6 and 12 hours after injection will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012112811597N1**

Registration date: **2013-02-24, 1391/12/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-02-24, 1391/12/06

Registrant information

Name

Nooshin Runassi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1453 6879

Email address

runassi.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz University of Medical Sciences

Expected recruitment start date

2013-04-19, 1392/01/30

Expected recruitment end date

2013-08-21, 1392/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Analgesia of Fentanyl with Ketamine during Injection of Propofol

Public title

Analgesia of Fentanyl and Ketamine during Propofol Injection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: - The patient's satisfaction - Age between 20 and 60 years old. Exclusion criteria: - History of substance abuse; hypnotics or narcotics throughout 24 hours before the surgery - History of drug abuse, or alcohol- dependency - Contraindication of Propofol or Ketamine - High Intracranial Pressure

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients are assigned randomly to 3 groups using a computerized allocation schedule for the coded syringes containing the study drugs. After randomization, the coded syringes are prepared by an anesthesiologist not involve in the administration of the drug, patient care and data collection.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

No.12, Chamber Sadaf, Golestan Blvd

City

Ahvaz

Postal code

6135733777

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

U91122

Health conditions studied

1

Description of health condition studied

Pain during injection

ICD-10 code

T80.9

ICD-10 code description

Unspecified complication during therapeutic injection, transport and injection

Primary outcomes

1

Description

Pain during propofol injection

Timepoint

Every 5 seconds after injection

Method of measurement

Verbal Rating Scale

Secondary outcomes

1

Description

Sedation

Timepoint

Every 5 seconds after injection

Method of measurement

Watching

Intervention groups

1

Description

Drug: Ketamine Dose: 0.1mg/kg IV Injection Number of using: Once Factory name: Rotexmedica Manufacturing Country's name: Germany Administration time: 45 seconds before Propofol administration

Category

Treatment - Drugs

2

Description

Drug: Fentanil Dose: 1mcg/kg IV Injection Number of using: Once Factory name: Chekad Manufacturing Country's name: Iran Administration time: 45 seconds before Propofol administration

Category

Treatment - Drugs

3

Description

Placebo: Normal Saline 0.9% Dose used: 2 ml IV Injection Number of using: Once Factory name: Samen Pharmacy CO. Manufacturing Country's name: Iran Administration time: 45 seconds before Propofol administration

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Educational Hospital

Full name of responsible person

Dr. Reza Akhundzadeh

Street address

No. 307, Kokab Street, Masters Alley, Golestan Blvd.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Dr. Mostafa Fegghi

Street address

No. 21, Ave. 1, Golestan Blvd.

City

Ahvaz

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, Ahvaz Jundishapur
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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nushin Runassi

Position

Resident of Anesthesia

Other areas of specialty/work

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Web page address

Person responsible for updating data

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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