

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of ketamine, Magnesium sulfate and Nesdonal on Propofol injection pain in patients undergoing elective surgery

Protocol summary

Summary

This study will be done to determine the comparative effects of ketamine, Nesdonal and Magnesium sulfate in reducing pain at the onset of anesthesia caused by Propofol injection in patients undergoing elective surgery. This single-blind (patient) clinical trial study will be conducted on a population of patients requiring non-emergency surgeries. The sample size for each group will be determined using 25 patients. Eligible patients based on Rand between software were randomly divided into three groups. An 18-gauge intravenous catheter will be inserted for all patients in the dorsum of the hand. Patients in three group will be received 0.5 ml/kg of ketamine, 30 mg/kg Magnesium sulfate and 0.5 ml/kg of Nesdonal respectively. Next, 2.5 mg/kg of Propofol 2% will be administered at a rate of 1 ml/s. Verbal Rating Scale (VRS) will be used to assess the severity of pain during injection

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060528283N1**

Registration date: **2016-07-19, 1395/04/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-19, 1395/04/29

Registrant information

Name

Hooshang Akbari

Name of organization / entity

Mazandaran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 0518

Email address

h.akbari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2013-10-01, 1392/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of ketamine, Magnesium sulfate and Nesdonal on Propofol injection pain in patients undergoing elective surgery

Public title

Comparison of the effects of ketamine, magnesium sulfate and nesdonal on propofol injection pain

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria ; class I and II ASA Exclusion criteria; patients with high intracranial pressure, unstable hemodynamics, severe mental disorders, history of allergy to drugs used, kidney, liver or heart dysfunction, addiction and use of Calcium or Magnesium blockers

Age

From **18 years** old to **65 years** old

Gender

Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 75

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
Research Deputy of Mazandaran University of Medical Sciences

Secondary trial Id
90-122

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mazandaran University of Medical Science

Street address
Moalem Street, Moalem Square, Sari , Iran

City
Sari

Postal code
4815696869

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
90-122

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
Y48.2

ICD-10 code description
Other and unspecified general anaesthetics

Primary outcomes

1

Description
Propofol injection pain

Timepoint
Once

Method of measurement
Verbal Rating Scale

Secondary outcomes

1

Description
Side effects

Timepoint
For 1 hours

Method of measurement
Surveillance the patients

Intervention groups

1

Description
An 18-gauge intravenous catheter will be inserted for all patients in the dorsum of the hand. One minute prior to Propofol injection, all patients will be received the study drug through a 5 ml syringe. In group one, patients will be received 0.5 ml/kg of ketamine (Trittau, Germany; production series 11-207). Next, 2.5 mg/kg of Propofol 2% (Melsugen, Germany; production series- 34209) will be administered at a rate of i 1 ml/s. Verbal Rating Scale (VRS) will be used to assess the severity of pain during injection

Category
Treatment - Drugs

2

Description
An 18-gauge intravenous catheter will be inserted for all patients in the dorsum of the hand. One minute prior to Propofol injection, all patients will be received the study drug through a 5 ml syringe. Patients in group two, will be receive 30 mg/kg of Magnesium sulfate (Pasteur Institute-Iran; production series 1228054891). Next, 2.5 mg/kg of Propofol 2% (Melsugen, Germany; production series- 34209) will be administered at a rate of i 1 ml/s. Verbal Rating Scale (VRS) will be used to assess the severity of pain during injection

Category
Treatment - Drugs

3

Description
An 18-gauge intravenous catheter will be inserted for all patients in the dorsum of the hand. One minute prior to Propofol injection, all patients will be received the study

drug through a 5 ml syringe. Patients in group three, will be received 0.5 ml/kg of Nesdonal (Trittau, Germany; production series -207) at a rate of 1 mg/s. Next, 2.5 mg/kg of Propofol 2% (Melsugen, Germany; production series- 34209) will be administered at a rate of 1 ml/s. Verbal Rating Scale (VRS) will be used to assess the severity of pain during injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Boali Hospital

Full name of responsible person

Dr hooshangakbari

Street address

Sari Boali Hospital, Emam SQ,Sari, Iran Sari

City

sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research Mazandaran University of Medical Sciences.

Full name of responsible person

Dr Ahmad Ali Enayeti

Street address

Moalem Street, Moalem Square, Sari, Iran

City

Sari

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 Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Attieh Nikkhah

Position

MSC in critical care nursing

Other areas of specialty/work

Street address

School of Nursing & Midwifery Mazandaran University of Medical Sciences, Vessal Street Sari, Iran.

City

Sari

Postal code

4815698689

Phone

+98 11 3326 8923

Fax

+98 11 3326 8936

Email

atinik1357@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Hooshang Akbari

Position

Assistant professor

Other areas of specialty/work

Street address

Mazandaran University of Medical Sciences sari, iran

City

Sari

Postal code

4815696869

Phone

+98 11 3326 8923

Fax

+98 11 3326 8936

Email

hooshangakbari48@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Attieh Nikkhah

Position

MSC in critical care nursing

Other areas of specialty/work

Street address

School of Nursing & Midwifery Mazandaran University of Medical Sciences,Vessal Street, Sari, Iran.

City

Sari

Postal code

4815686968

Phone

+98 11 3326 8923

Fax

+98 11 3326 8936

Email

atinik1357@gmail.com

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