

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of propofol and fentanyl with propofol and ketamine in sedation and analgesia in trauma patients

Protocol summary

Summary

This is a single blind randomized clinical trial which will be done on trauma patients admitted to the emergency room of Imam Khomeini Hospital, Sari. The patient is not aware of drugs' type and dosage and just the person performing the procedure will know. Patients were randomly allocated (using a random number table) in two groups. The first group received 0.5mg/kg propofol and 1 µg/kg fentanyl and the second group received 0.5 mg/kg propofol and 1 mg/kg ketamine that will be administered through a peripheral vein with a no.20 catheter. Sample size was calculated 66 in each group. Every patient will be monitored by the author in 0, 5, 15 and 30 minutes after drug administration in account of sedation rate, pain rate and drugs complications. Data was recorded in each patient's data form. Recovery time and the need for additional doses also will be recorded. sedation rate is classified by the joint commission(TJC). Pain is rated according to numerical scale 0 to 10. All obtained data will be analyzed using SPSS 17.0. Appropriate Central and peripheral scattering indicators will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112224606N2**

Registration date: **2016-12-07, 1395/09/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-07, 1395/09/17

Registrant information

Name

Hamed Aminiahidashti

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-11-10, 1395/08/20

Expected recruitment end date

2017-05-10, 1396/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of propofol and fentanyl with propofol and ketamine in sedation and analgesia in trauma patients

Public title

Comparison of propofol and fentanyl with propofol and ketamine in sedation and analgesia in trauma patients

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 1. Age between 18 and 60 years, have indicated a painful procedure and this treatment included painful reduction of dislocation and fractures can be done in an emergency. 2 Persons according to the American Society of Anesthesiologists Physical Status Classification (ASA) class 1 and 2 have Exclusion criteria:

1 - persons under 18 years and above 60 years of age 2- people with Anesthesiologists Physical Status Classification (ASA) class more than two 3-people with kidney and liver disease 4-person with alcohol consumption 5-people addicted to drugs 6- pregnant and lactating women 7- those who have contraindications to the use of ketamine and propofol and fentanyl

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **132**

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Jooybar treeway, Imam Square

City

Sari

Postal code

4815724971

Approval date

2016-11-16, 1395/08/26

Ethics committee reference number

IR.MAZUMS.REC.95.1555

Health conditions studied

1

Description of health condition studied

Lower limb injury - Upper limb injury

ICD-10 code

T13.9 -

ICD-10 code description

Unspecified injury of lower limb, level unspecified injury of NOS - Unspecified injury of upper limb , level unspecified injury of arm NOS

Primary outcomes

1

Description

sedation

Timepoint

Before intervention, 5 minutes after intervention, 15 minutes after intervention, 30 minutes after intervention, 120 minutes after intervention

Method of measurement

sedation rate is classified by the joint commission(TJC). Grade 1 (Minimal sedation): patients obey orders, but patient consciousness has been disrupted. Grade 2 (Moderate sedation): the patient wakes up in responding to touch and has a withdrawal reflex to pain. Grade 3 (Deep sedation): patient wakes up with recurrent painful stimulation and cannot keep his/her airway by own. Grade 4 (General anesthesia): patient not respond to repeated painful provocations and requires mechanical ventilation, and cardiovascular status can also be disrupted.

2

Description

Pain

Timepoint

Before intervention, 5 minutes after intervention, 15 minutes after intervention, 30 minutes after intervention, 120 minutes after intervention

Method of measurement

Pain is rated according to numerical scale 0 to 10, so 10 is the worst pain condition and 0 is no pain condition.

Secondary outcomes

1

Description

Oxygen Saturation

Timepoint

Before intervention, 5 minutes after intervention, 15 minutes after intervention, 30 minutes after intervention, 120 minutes after intervention

Method of measurement

Puls oxymeter

2

Description

Heart Rate

Timepoint

Before intervention, 5 minutes after intervention, 15 minutes after intervention, 30 minutes after intervention, 120 minutes after intervention

Method of measurement

number per minutes

3

Description

Respiratory rate

Timepoint

Before intervention, 5 minutes after intervention, 15 minutes after intervention, 30 minutes after intervention, 120 minutes after intervention

Method of measurement

number per minutes

4

Description

Blood pressure

Timepoint

Before intervention, 5 minutes after intervention, 15 minutes after intervention, 30 minutes after intervention, 120 minutes after intervention

Method of measurement

sphygmomanometer mmhg

5

Description

Vomiting

Timepoint

Before intervention, 5 minutes after intervention, 15 minutes after intervention, 30 minutes after intervention, 120 minutes after intervention

Method of measurement

Observation

6

Description

Sialorrhea

Timepoint

Before intervention, 5 minutes after intervention, 15 minutes after intervention, 30 minutes after intervention, 120 minutes after intervention

Method of measurement

Observation

Intervention groups

1

Description

Second group received 0.5 mg/kg propofol and 1 mg/kg ketamine

Category

Treatment - Drugs

2

Description

First group received 0.5mg/kg propofol and 1 µg/kg fentanyl

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeni Hospital

Full name of responsible person

Hamed Aminiahidashti

Street address

Amir mazandarani Bolivard

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for researche, Mazandaran University of Medical Siences

Full name of responsible person

Ahmadali Enayati

Street address

Vice chancellor for researche, Mazandaran University of Medical Siences, Moallem Square

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 researche, Mazandaran University of Medical Siences

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

Hamed Aminiahidashti

Position

Assistant Professor

Other areas of specialty/work

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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)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty