

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison the effect of Ketamin and placebo on succinylcholine induced Myalgia in candidates of outpatient surgeries - A Double Blind Randomized Controlled Trial

Protocol summary

Summary

The objective of this study was to investigate the effect of ketamine on muscle pain (Myalgia) caused by succinylcholine in patients who were candidates of outpatient surgeries. The study population included all patients referred to Besat Hospital for outpatient surgery who fulfilled inclusion criteria. Inclusion criteria consisted of being candidate for elective outpatient surgery; physical condition in accordance with classes I and II of American Society of Anesthesiologists Classification and exclusion criteria included history of allergy to drugs, history of malignant hyperthermia and history of neuromuscular disease (myopathy). A total of 144 patients were selected and randomly divided into two groups through randomized blocking method. Patients and researcher were not aware of patients' grouping. ketamine 0.5 Mg per Kg was injected to patients in the intervention group and 5 mm distilled water (as placebo) was injected to the control group. Then, 1.5 mic per kg fentanyl was injected as pre-medication prior to induction of anesthesia for all patients in both groups. Three minutes after administration of ketamine and fentanyl, induction of anesthesia was performed using propofol 2 to 2.5 mg per kg. After the disappearance of the corneal reflex, succinylcholine 1.5 mg per kg was used for muscle relaxation. Patients were under supervision during the surgery and in recovery room for probable complications (nausea, vomiting, chills, delirium, nystagmus, and respiratory depression) caused by injected drugs. Complications were recorded on check list. Myalgia was evaluated 24 hours after surgery according to 4-point rating scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062412789N5**

Registration date: **2014-09-13, 1393/06/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-13, 1393/06/22

Registrant information

Name

Masoud Rasolabady

Name of organization / entity

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Iran (Islamic Republic of)

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+98 87 3366 4654

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kurdistan University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Ketamin and placebo on

succinylcholine induced Myalgia in candidates of outpatient surgeries - A Double Blind Randomized Controlled Trial

Public title

Ketamine efficacy on succinylcholine induced myalgia in outpatient surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: candidates for elective outpatient surgery, physical condition in accordance with classes I and II of American Society of Anesthesiologists Classification Exclusion criteria: history of allergy to drugs, a history of malignant hyperthermia, history of neuromuscular disease (myopathy)

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

With randomized block method in categories of four persons, patients were divided into two intervention and control groups. Injection was performed by an anesthesiologist who was informed about patients grouping. Myalgia was measured by an observer who was not aware about injected drug (ketamine or distilled water). Researcher also was not aware of patients grouping and patients did not know to which group (control or intervention) they are located. Monitoring team was aware of patients grouping.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Pasdaran St., Kurdistan University of Medical Sciences

City

Sanandaj

Postal code**Approval date**

2014-06-30, 1393/04/09

Ethics committee reference number

14/13029

Health conditions studied**1****Description of health condition studied**

Myalgia

ICD-10 code

M79.1

ICD-10 code description

Myalgia

Primary outcomes**1****Description**

Hemodynamic changes

Timepoint

Before induction of anesthesia, immediately before intubation and 5 minutes after intubation

Method of measurement

Heart rate and blood pressure that measured by machine would be read on monitor and recorded in check list. After complete relaxation, intubation is performed and again after 5 minutes, blood pressure and heart rate would measure and recorded in check list.

2**Description**

Myalgia

Timepoint

24 hours after surgery

Method of measurement

4-point scale: nil = no muscle pains or stiffness; mild = muscle pains or stiffness at one site but not causing disability or limiting activities; moderate = muscle pains or stiffness at more than one site but not causing disability or limiting activities; severe = muscle pains or stiffness at one site or more and causing disability or limiting activities, e.g., difficulty getting out of bed or turning the head.

Secondary outcomes**1****Description**

Complications

Timepoint

During the surgery and in recovery room

Method of measurement

Observation and monitoring the patient in the recovery room by the researcher

Intervention groups

1

Description

ketamine 0.5 Mg per Kg (By adding distilled water the volume was reached to 5 mm) was injected to patients in the intervention group. Then 1.5 mic per kg fentanyl was injected as pre-medication prior to induction of anesthesia and 3 minutes after administration of ketamine and fentanyl, induction of anesthesia using propofol 2 to 2.5 mg per kg was performed. After the disappearance of the corneal reflex succinylcholine 1.5 mg/kg was used for muscle relaxation.

Category

Treatment - Drugs

2

Description

In the intervention group 5 mm distilled water was injected. Then 1.5 mic per kg fentanyl was injected as pre-medication prior to induction of anesthesia and 3 minutes after administration of ketamine and fentanyl, induction of anesthesia using propofol 2 to 2.5 mg per kg was performed. After the disappearance of the corneal reflex succinylcholine 1.5 mg/kg was used for muscle relaxation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Sanaz Arvin

Street address

Keshavarz St., Mardokh Four Way, Besat Hospital

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Kurdistan University of Medical Sciences

Full name of responsible person

Fardin Gharibi

Street address

Pasdaran St., Kurdistan University of Medical Sciences

City

Sanandaj

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, Kurdistan 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

Kurdistan University of Medical Sciences

Full name of responsible person

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Position

Medical Student

Other areas of specialty/work

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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