Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 4654

Email address

rasolabady@muk.ac.ir

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
Sanaz Arvin

Position
Medical Student

Other areas of specialty/work

Street address
Keshavarz St., Mardokh Four Way, Besat Hospital

City
Sanandaj

Postal code

Phone
+98 87 3328 5910

Fax

Email
sanazarvin66@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kurdistan University of Medical Sciences

Full name of responsible person
Karim Nasseri

Position
Anesthesiologist/assistant professor

Other areas of specialty/work

Street address
Keshavarz St., Mardokh Four Way, Besat Hospital

City
Sanandaj

Postal code

Phone
+98 87 3328 8199

Fax

Email
nasseri_k@muk.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kurdistan University of Medical Sciences

Full name of responsible person
Sanaz Arvin

Position
Medical Student

Other areas of specialty/work

Street address
Keshavarz St., Mardokh Four Way, Besat Hospital

City
Sanandaj

Postal code

Phone
+98 87 3328 5910

Fax

Email
sanazarvin66@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