Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of pretreatment effects of remifentanil on succinylcholine-induced fasciculation and post operative pain

Protocol summary

Summary

Succinylcholine is a popular muscle relaxant for ambulatory anesthesia. Muscle fasciculation and post operative pain are common side effects of succinylcholine administration. The purpose of this double blind randomized controlled trial is to evaluate the efficacy of remifentanil in preventing succinylcholine-induced fasciculation and post operative pain in the patients undergoing general anesthesia. Based on inclusion and exclusion criteria 60 patients are included in the study and randomized using computer-generated random numbers into two groups of 30 patients according to pretreatment: NaCl 0.9% (control), and remifentanil 1µg/kg (study) that will be always adjusted to a 3-mL volume. The observer and the patients are unaware of the pretreatment used. The induction regimen is similar for all patients as follow: At time 0, injection of fentanyl 1 µg/kg and the pretreatment regimen according to the patient's group; 2 min later, anesthesia will be induced with propofol 2 mg/kg IV and muscle relaxation will be achieved with succinylcholine 1.5 mg/kg. Following succinylcholine, duration (second) and severity of fasciculation according to a 4-point rating scale will be measured and recorded, and then post operative pain will be measured and recorded in one, 6 and 24 hour after operation according to 4-point rating scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138712241766N1**
Registration date: **2009-09-11, 1388/06/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-09-11, 1388/06/20

Registrant information

Name
Karim Nasseri
Name of organization / entity
Kurdistan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 87 1666 3728
Email address
nasseri_k@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Kurdistan university of medical siences

Expected recruitment start date

2008-12-22, 1387/10/02

Expected recruitment end date

2009-12-23, 1388/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of pretreatment effects of remifentanil on succinylcholine-induced fasciculation and post operative pain

Public title

Study of the effects of adding remifentanil to anesthetic drugs before succinylcholine on post operative myalgia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: American Society of Anesthesiologists (ASA) physical status I or II, ambulatory urological or gynecological surgery under general anesthesia. Exclusion criteria : arrhythmia, hypo- or hypertension, hyperkalemia, increased intraocular pressure, increased intracranial pressure, presenting a difficult airway, pregnant, treatment with any drug known to interact with neuromuscular function, and significant renal, neuromuscular, or hepatic disease.

Age
From **15 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of kurdistan university of Medical Siensces

Street address
Passdaran Blv

City
Sanandaj

Postal code

Approval date
2008-03-17, 1386/12/27

Ethics committee reference number
5953//پ14/پ

Health conditions studied

1

Description of health condition studied
post operative pain

ICD-10 code
M79.1

ICD-10 code description
Myalgia

2

Description of health condition studied
Skeletal muscle relaxants

ICD-10 code
Y55.1

ICD-10 code description
Skeletal muscle relaxants [neuromuscular blocking agents]

Primary outcomes

1

Description
Muscle fasciculation

Timepoint
after adminstration of succinylcoline

Method of measurement
Observational by 4-point scale: no fasciculation= 0; mild, fine fasciculation of the eyes, neck, face or fingers without limb movement = 1; moderate fasciculation occurring at more than two sites or obvious limb movement = 2; vigorous or severe, sustained, and widespread fasciculation = 3.

2

Description
Post operative pain

Timepoint
1 ,6 and 24 hours after operation

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
Blood pressure changes

Timepoint
before induction of anesthesia and after ending fasciculation

Method of measurement
automated oscilometer

2

Description
Heart rate changes

Timepoint

Before induction of anesthesia and after ending fasciculation

Method of measurement

BSI (passport2) automated monitor

Intervention groups

1

Description

Remifentanil: in remifentanil group induction regimen is as follow: At time 0, injection of fentanyl 1 µg/kg and pretreatment (remifentanil 1µg/kg that be adjusted to a 3-mL volume) 2 min later, then propofol 2 mg/kg and after loss of eyelid reflexes succinylcholine 1.5 mg/kg

Category

Treatment - Drugs

2

Description

0.9 saline normal: In saline group induction regimen is as follow: At time 0, injection of fentanyl 1 µg/kg and pretreatment (3 ML 0.9 saline normal) 2 min later, then propofol 2 mg/kg and after loss of eyelid reflexes succinylcholine 1.5 mg/kg

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Beasat hospital

Full name of responsible person

Karim Nasseri

Street address

Kshavarze St

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan university of medical siences

Full name of responsible person

Dr.Haidari

Street address

Pasdaran Blv.

City

Sanandaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kurdistan 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

Faculty of medicine

Full name of responsible person

Mehdi Tayebi Arasteh

Position

Anesthsiologist/Assesstant professor

Other areas of specialty/work

Street address

Pasdaran Blv.

City

Sanandaj

Postal code

Phone

+98 87 1666 6463

Fax

Email

mehtayeb@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of medicine

Full name of responsible person

Karim Nasseri

Position

Anesthesiologist/assesstant professor

Other areas of specialty/work

Street address

Pasdaran Blv.

City

Sanandaj

Postal code

Phone

+98 87 1666 3728

Fax

Email

nasseri_k@muk.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of nursing

Full name of responsible person

Shoaleh Shami

Position

Master of nursing

Other areas of specialty/work

Street address

Pasdaran Blv.

City

Sanandaj

Postal code

Phone

Fax

Email

shami471@yahoo.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