

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Study of pretreatment effects of remifentanyl 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 remifentanyl 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 remifentanyl 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

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Recruitment status

Recruitment complete

Funding source

Kurdistan university of medical sciences

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 remifentanyl on succinylcholine-induced fasciculation and post operative pain

Public title

Study of the effects of adding remifentanyl 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

Remifentanyl: in remifentanyl group induction regimen is as follow: At time 0, injection of fentanyl 1 µg/kg and pretreatment (remifentanyl 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 sciences

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 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

Faculty of medicine

Full name of responsible person

Mehdi Tayebi Arasteh

Position

Anesthesiologist/Assesstant professor

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