Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation the effects of combination of Propofol-Remifentanil on Succinylcholine induced post operative fasciculations, myalgia and biochemical changes in lower abdominal surgeries

Protocol summary

Summary

The aim of this study is to evaluate the effect of remifentanil on succinylcholine-induced biochemical changes and postoperative myalgia. Among patients who are scheduled for elective minor surgeries of lower abdomen, and according to the inclusion criteria, 60 patients will be selected, and randomly divided into two groups. Except the study drugs, the dose and type of main anesthetics are the same for all patients and including: fentanyl 1mcg/kg, propofol 2mg/kg and succynilcholine 1.5mg/kg. Pre-treatment for study group is remifentanil 1mcg/kg and for control group is 3ml of saline normal. Mean arterial blood pressure and heart rate will be measured and recorded three times (before induction of anesthesia, after induction of anesthesia, and after intubation of patient). After injection of succynilcholine the intensity and duration of muscle fasciculation will be measured and recorded for both of groups. Three blood samples will be obtained from all patients in three different times (before induction of anesthesia, after intubation of patient and 24hour after operation). First sample for serum potassium level (K) and Creatine PhosphoKinase(CPK), second for serum potassium and the thirds for CPK. A third party who is not aware of patients grouping will evaluate post operative myalgia, using a four-point Scale, at 5 different times. Results will be compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810141766N3**
Registration date: **2010-04-05, 1389/01/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-04-05, 1389/01/16

Registrant information

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2009-10-21, 1388/07/29

Expected recruitment end date

2010-10-21, 1389/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effects of combination of Propofol-Remifentanil on Succinylcholine induced post operative fasciculations, myalgia and biochemical changes in lower abdominal surgeries

Public title

Evaluation the effect o f Remifentanil on Succinylcholine-

indused biochemical changes during anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Scheduled for elective surgery of lower abdomen (such as inguinal hernia, hydrocele and ...), signing informed consent, ASA class of 1 or 2. Exclusion criteria: addiction (opioides, alcohol, or psychological drugs), history of allergic reaction to study drugs, cholinesterase deficiency, hypertension, neuromuscular disease, pregnancy, and using drugs that interact with neuromuscular function.

Age

From **18 years** old to **60 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 Sciences, Research Department

Street address

Passdaran Street

City

Sanandaj

Postal code

Approval date

empty

Ethics committee reference number

پ14، بند 80175

Health conditions studied

1

Description of health condition studied

Complication of muscle relaxant drugs (succinylcholine), not elsewhere classified

ICD-10 code

T78.8

ICD-10 code description

Other adverse effects, not elsewhere classified

Primary outcomes

1

Description

Serum potassium level changes

Timepoint

befor induction of anesthesia and 5 minutes after injection of succinylcholine

Method of measurement

Laboratory

2

Description

Serum creatine phosphokinase level (CPK) changes

Timepoint

before induction of anesthesia and 24 hours after that

Method of measurement

Laboratory

Secondary outcomes

1

Description

Blood pressure changes

Timepoint

Before induction of anesthesia, after induction of anesthesia and after tracheal intubation

Method of measurement

Clinically (automated pressure gauge)

2

Description

Heart rate changes

Timepoint

before induction of anesthesia, after induction of anesthesia and after tracheal intubation

Method of measurement

Clinically (by automated monitoring)

3

Description

Postoperative myalgia

Timepoint

In 5 times, 2, 6, 24, 48 and 72 hours after operation

Method of measurement

By a 4-point scale questionnaire

4

Description

Duration of fasciculation

Timepoint

after injection of succinylcholine

Method of measurement

Chronometer

Intervention groups

1

Description

Injection of Remifentanil 1mcg/kg two minutes before the induction of anesthesia

Category

Treatment - Drugs

2

Description

Injection of 3 ml saline normal 0.9% (placebo) two minutes before the induction of anesthesia

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Beasat Hospital

Full name of responsible person

Babak Qotbi

Street address

Keshavarz Street

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Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences, Research Department

Full name of responsible person

Ataaolah Haidari

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Passdaran Street

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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, Research Department

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

Nursing and Midwifery School, Kurdistan University of Medical Sciences

Full name of responsible person

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Position

Master of Nursing

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