

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of Alfentanil, Lidocaine, and combination of Alfentanil plus Lidocaine to control hemodynamic responses during awake extubation

Protocol summary

Summary

The aim of this study is to compare the effect of Alfentanil, Lidocaine and combination of Alfentanil plus Lidocaine to control hemodynamic responses during awake extubation. Inclusion criteria are upper limb orthopedic surgery and age between 20 - 40 years old. Exclusion criteria are smoking, addiction, cardiac respiratory disease, age less than 20, age more than 40 and drug allergy. 172 patients, divide into four equal groups. Group A; receives Alfentanil 5 microgram per kilogram, group B; receives Lidocaine 1 milligram per kilogram, group C; receives Alfentanil plus Lidocaine, and group D; receives normal saline. The mean systolic blood pressure, mean diastolic blood pressure, mean arterial pressure and heart rate measure and record before extubation and during extubation. Also, it measures and records 1, 5, 10, 15, and 20 minutes after extubation, bucking statue after extubation is recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040725095N1**

Registration date: **2016-04-07, 1395/01/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-07, 1395/01/19

Registrant information

Name

Mahmoud Aghaziarati

Name of organization / entity

Qazvin University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2015-01-20, 1393/10/30

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Alfentanil, Lidocaine, and combination of Alfentanil plus Lidocaine to control hemodynamic responses during awake extubation

Public title

Comparing the effect of Alfentanil, Lidocaine, and combination of Alfentanil plus Lidocaine to control hemodynamic responses during awake extubation

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Having upper limb orthopedic surgery; age between 20 - 40 years Exclusion criteria: smoking; addiction; cardiac respiratory disease; age less than 20; age more than 40; drug allergy

Age

No age limit
Gender
Both
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **172**
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 the University of Medical Sciences

Street address

Qazvin, Shahid Bahonar Boulvar

City

Qazvin

Postal code

3419915315

Approval date

2014-12-31, 1393/10/10

Ethics committee reference number

9674/20/28

Health conditions studied

1

Description of health condition studied

Hemodynamic changes after extubation

ICD-10 code

T88.9

ICD-10 code description

Complication of surgical and medical care, unspecified

Primary outcomes

1

Description

mean systolic blood pressure (SBP)

Timepoint

before and during extubation and, 1, 5, 15, and 20 minutes after extubation

Method of measurement

check list

2

Description

mean diastolic blood pressure (DBP)

Timepoint

before and during extubation and, 1, 5, 15, and 20 minutes after extubation

Method of measurement

check list

3

Description

mean artetial pressure

Timepoint

before and during extubation and, 1, 5, 15, and 20 minutes after extubation

Method of measurement

check list

4

Description

heart rate

Timepoint

before and during extubation and, 1, 5, 15, and 20 minutes after extubation

Method of measurement

chec list

Secondary outcomes

1

Description

bucking

Timepoint

after extubation

Method of measurement

check list

Intervention groups

1

Description

Group A received Alfentanil 5 µg/kg on reverse injection time

Category

Treatment - Drugs

2

Description

Group B received Lidocaine 1mg/kg on reverse injection time

Category

Treatment - Drugs

3**Description**

Group C received Alfentani 5 µg/kg plus Lidocaine 1mg/kg on reverse injection time

Category

Treatment - Drugs

4**Description**

Group d received normal saline on reverse injection time

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sgahid Rajaei Hospita of Qazvin

Full name of responsible person

Dr Mahmood Aghaziarati

Street address

Rajaei Hospital, Padegan Street, Qazvin

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Qazvin

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Dr Marzie Beighom Khezri

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Shahid Bahonar Boulvar, Qazvin

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Qazvin

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Dr Mahmood Aghaziarati

Position

Anesthesia Assistant

Other areas of specialty/work**Street address**

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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