Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

comparison of different doses of remifentanyl with the combination of propofol and meperidine on endotracheal intubation without muscle relaxant

Protocol summary

Summary

Background & Purpose: Using muscle relaxants for endotracheal intubation is not always possible, therefore we can use short-acting opioids along with propofol. Design: double-blind clinical trial method: patients are allocated randomly into 2 30-person groups. The doctor and the patients were unaware of the injected dose of the drug. Inclusion criteri: 60 patients aged between 18-35; orthopedic operation; ASA class I,II exclusion criteria: hypertention; cardiovascular problems; difficult and irritant air-way; drug abuse; BMI above 30 interventions: after initial assessment and standard monitoring, 10cc/Kg Ringer's solution is infused. 0.03mg/Kg midazolam and 1mg/Kg meperidine is administered to all of them. After 5 minutes, 1µg/Kg and 1.5µg/Kg remifentanyl is administered to the first and the second group, respectively. Moreover, 2mg/Kg propofol is infused over 60 seconds for both groups. Primary consequences : changes in patient's blood pressure and heart rate in specific time intervals are recorded

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310234923N4**
Registration date: **2013-12-12, 1392/09/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-12-12, 1392/09/21

Registrant information

Name

Bahman Hasannasab

Name of organization / entity

Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor Of Research Babol University Of Medical Sciences

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of different doses of remifentanyl with the combination of propofol and meperidine on endotracheal intubation without muscle relaxant

Public title

comparison of different doses of remifentanyl with the combination of propofol and meperidine on endotracheal intubation without muscle relaxant

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria : patients aged between 18-35 , ASA class I and II , general anesthesia ,undergoing orthopedic

surgery exclusion criteria : The patients with hypertention, cardiovascular problems, irritable air way, drug abuse, BMI above 30, addiction and possibility of difficult airway

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University Of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code

Approval date

2009-07-04, 1388/04/13

Ethics committee reference number

3823/30/ژ/پ

Health conditions studied

1

Description of health condition studied

endotracheal intubation

ICD-10 code

Y45.0

ICD-10 code description

Opioids and related analgesics

Primary outcomes

1

Description

endotracheal intubation

Timepoint

60 seconds after drug injection

Method of measurement

evaluation of jaw relaxation ; laryngoscopy status ,vocal cord ,and coughing

Secondary outcomes

1

Description

blood pressure

Timepoint

before intubation, after drug injection, in one, three and five minutes after endotracheal intubation.

Method of measurement

cuff manometer

2

Description

heart rate

Timepoint

before intubation, after drug injection, in one, three and five minutes after endotracheal intubation.

Method of measurement

, puls oximetry

Intervention groups

1

Description

1µg/Kg remifentanil injection

Category

Treatment - Drugs

2

Description

1.5µg/Kg remifentanil injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti Hospital

Full name of responsible person

Dr Bahman Hasannasab

Street address

Shahid Ghasemi Avenue

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor Of Research Babol University Of Medical Sciences

Full name of responsible person
Dr Amrolah Mostafazadeh

Street address
Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

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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
Vice-chancellor Of Research Babol 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
Babol University Of Medical Sciences

Full name of responsible person
Dr Bahman Hasannasab

Position
Assistant Professor of Anesthesiology

Other areas of specialty/work

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Position
Assistant Professor of Anesthesiology

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Person responsible for updating data

Contact

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