

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of sufentanil and remifentanyl in combination with propofol to facilitate use of supraglottic airway devices

Protocol summary

Summary

Purpose: The purpose of this study is to evaluate the effects of two narcotics, remifentanyl and sufentanil on ease of insertion of two types of supraglottic airway devices. Plan: This is a randomized block, double-blind, without placebo and clinical trial phase II study. Inclusion criterion: patients who were candidates for elective surgery. Exclusion criteria: patients who were hemodynamically unstable, had a history of heart and respiratory disorders, required airway control by endotracheal intubation and those who may need to change position during surgery. The sample size in this study is 200. Interventions: Anesthesia induction was performed using propofol 2.5 mg/kg for all patients and then 1st group received remifentanyl and laryngeal mask, 2nd group remifentanyl and SLIPA, 3rd group sufentanil and laryngeal mask, and 4th group sufentanil and SLIPA. Primary outcome: The amount of jaw opening, ease of insertion of supraglottic devices, cough, laryngospasm, and the gag reflex, heart rate and arterial blood pressure were recorded one, three, and five minutes after insertion of supraglottic devices.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110027686N1**

Registration date: **2011-12-31, 1390/10/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-31, 1390/10/10

Registrant information

Name

Hesameddin Modir

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 1313 9793

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dr.hemodir@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2011-05-05, 1390/02/15

Expected recruitment end date

2011-10-07, 1390/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sufentanil and remifentanyl in combination with propofol to facilitate use of supraglottic airway devices

Public title

Comparison of sufentanil and remifentanyl in combination with propofol to facilitate use of supraglottic airway devices

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: patients who were candidates for elective surgery Exclusion criteria: hemodynamic instability; history of heart and respiratory disorders;

required airway control by endotracheal intubation and need to change position during surgery

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 200

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**

Ethical Committee of Arak University of Medical Sciences

Street address

Alamolhoda Ave, Arak University of Medical Sciences

City

Arak

Postal code**Approval date**

2011-05-04, 1390/02/14

Ethics committee reference number

89-81-2

Health conditions studied**1****Description of health condition studied**

Tracheal intubation

ICD-10 code

T88.4

ICD-10 code description

Failed or difficult intubation

Primary outcomes**1****Description**

Blood Pressure

Timepoint

Before induction of anesthesia and one, three and five minutes after induction of anesthesia

Method of measurement

Blood pressure manometer

2**Description**

Heart rate

Timepoint

Before induction of anesthesia and one, three and five minutes after induction of anesthesia

Method of measurement

Counting the heart rate in one minute

3**Description**

Jaw Opening

Timepoint

One minute after induction of anesthesia

Method of measurement

variable was measured qualitatively by 3 grades: Full(3) Partial(2) Nil(1)

4**Description**

Ease of supraglottic device insertion

Timepoint

One minute after induction of anesthesia

Method of measurement

variable was measured qualitatively by 3 grades: Easy(1)Difficult(2)Impossible(3)

5**Description**

Cough

Timepoint

One minute after induction of anesthesia

Method of measurement

variable was measured qualitatively by 3 grades: Nil(1) ++(2) +++(3)

6**Description**

Laryngospasm

Timepoint

One minute after induction of anesthesia

Method of measurement

variable was measured qualitatively by 3 grades: Nil(1) Moderate(2) Vigorous(3)

7**Description**

Gagging

Timepoint

One minute after induction of anesthesia

Method of measurement

variable was measured qualitatively by 3 grades: Nil(1)
++(2) +++(3)

Secondary outcomes

empty

Intervention groups**1****Description**

General anesthesia was induced for all patients with 2.5 mg/kg of IV propofol in the first group and patients received 1 µg/kg remifentanyl and LMA was used for airway management

Category

Treatment - Drugs

2**Description**

General anesthesia was induced for all patients with 2.5 mg/kg of IV propofol in the second group and patients received 1 µg/kg remifentanyl and SLIPA was used for airway management

Category

Treatment - Drugs

3**Description**

General anesthesia was induced for all patients with 2.5 mg/kg of IV propofol in the third group and patients received 1.5 µg/kg remifentanyl and LMA was used for airway management

Category

Treatment - Drugs

4**Description**

General anesthesia was induced for all patients with 2.5 mg/kg of IV propofol in the fourth group and patients received 1.5 µg/kg remifentanyl and SLIPA was used for airway management

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Vali-Asr hospital

Full name of responsible person

Dr Hesamaldin Modir

Street address

Vali-Asr hospital, Pirouzi Ave

City

Arak

2**Recruitment center**

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Hesamaldin Modir

Street address

Amiralmomenin Hospital, Basij Square

City

Arak

3**Recruitment center**

Name of recruitment center

Amirkabir Hospital

Full name of responsible person

Dr Hesamaldin Modir

Street address

Amirkabir Hospital, Parastar Square

City

Arak

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Arak University of Medical Sciences,Vice chancellor for research

Full name of responsible person

Dr Saeed Changizi Ashtiani

Street address

Arak University Of Medical Science, Basij Square

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Sciences,Vice chancellor for research

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

Arak University of Medical Sciences

Full name of responsible person

Dr Hesamaldin Modir

Position

Anesthesiologist

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Position

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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