

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of hemodynamic parameters between low flow Isoflurane and low flow Sevoflurane in patients during anesthesia with controlled ventilation Laryngeal Mask Airway

Protocol summary

Summary

Laryngeal mask airway is a simple device for airway protection and anesthesia with low complications, which is widely used in elective surgeries. In low flow anesthesia, an inhaled anesthetic gas with a breathing system in which the rate of re-breathing is at least 50% is used. Several studies compared the hemodynamic stability during isoflurane anesthesia with Sevoflurane which have shown different results. Therefore, this study aims to compare the hemodynamic stability between low flow Isoflurane and low flow Sevoflurane anesthesia during controlled ventilation with Laryngeal Mask Airway. Eighty adult patients with ASA I and II class, aging 20-75 years without the risk of airway problems, history of malignant hyperthermia, diabetes mellitus and kidney problems, candidates for elective surgery will be included in this study. Patients will be randomly divided into two groups, one group of low flow anesthesia with isoflurane and other group of low flow anesthesia with Sevo.f. Standard monitoring during induction of anesthesia in all patients will be done. Systolic blood pressure, diastolic blood pressure, heart rate, ETCO₂ and mean arterial pressure will be measured every 5 minutes in each group. Therefore, this study aims to compare the hemodynamic stability between low flow Isoflurane and low flow Sevoflurane anesthesia during controlled ventilation with Laryngeal Mask Airway. Eighty adult patients with ASA I and II class, aging 20-60 years without the risk of airway problems, history of malignant hyperthermia, diabetes mellitus and kidney problems, candidates for elective surgery will be included in this study. Patients will be randomly divided into two groups, one group of low flow anesthesia with isoflurane and other group of low flow anesthesia with Sevo.f. Standard monitoring during induction of anesthesia in all patients will be done. Systolic blood pressure, diastolic blood pressure, heart rate, ETCO₂ and mean arterial pressure

will be measured every 5 minutes in each group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202202582N4**

Registration date: **2012-03-17, 1390/12/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-17, 1390/12/27

Registrant information

Name

Ata Mahmoodpoor

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 116 0888

Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-02-04, 1390/11/15

Expected recruitment end date

2012-07-05, 1391/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of hemodynamic parameters between low flow Isoflurane and low flow Sevoflurane in patients during anesthesia with controlled ventilation Laryngeal Mask Airway

Public title
Comparison of low flow Isoflurane and low flow Sevoflurane anesthesia during controlled ventilation with Laryngeal Mask Airway

Purpose
Treatment

Inclusion/Exclusion criteria
inclusion criteria: Adult patients with ASA I and II class; aging 20-60 years; candidates for elective surgery
Exclusion criteria: the possibility of airway problem; history of malignant hyperthermia; lack of proper monitoring; co2 absorbant failure; uncompensated diabetes mellitus; prolonged starvation; chronic and acute alcoholism; smoking; presence of severe kidney problems

Age
From **20 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Tabriz University of Medical Sciences
Street address
Golgasht street
City
Tabriz

Postal code
Approval date
2011-02-28, 1389/12/09
Ethics committee reference number
4993/4/5

Health conditions studied

1

Description of health condition studied
Hemodynamic changes
ICD-10 code
R03
ICD-10 code description
Abnormal blood-pressure reading, without diagnosis

Primary outcomes

1

Description
Mean Arterial Pressure
Timepoint
every 5 minutes
Method of measurement
in mmHg using manometer

2

Description
heart rate
Timepoint
every 5 minutes
Method of measurement
beat in minute

Secondary outcomes

1

Description
side effects
Timepoint
every 5 minutes
Method of measurement
physical examination

Intervention groups

1

Description
in intervention group: sevoflurane 2-2.5% in initial phase and 3-3.5% in low flow phase
Category
Treatment - Drugs

2

Description

in control group: isoflurane with fresh gas flow of 6 L/min in initial phase and 1 L/min in low flow phase

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikookary hospital

Full name of responsible person

Ata Mahmoodpoor

Street address

Abbasi street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences, Research chancellor

Full name of responsible person

Alireza Ostadrahimi

Street address

Golgasht street

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences, Research chancellor

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

Tabriz University of Medical Sciences

Full name of responsible person

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Position

medical student

Other areas of specialty/work

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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