Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative evaluation of effects of different tidal volumes of mechanical ventilation on hemodynamic indices during deliberate hypotension by using nitroprosside & nitroglycerine in ear microsurgery patients

Protocol summary

Summary
This study was designed to compare effects of different tidal volumes (5, 10 and 15 cc/kg) on hemodynamic indices (HR, BP, SV, CO, ...) during controlled hypotension which induced by continuous infusion of Nitroglycerin (0.5 to 30 µg/kg/min) or Na Nitroprusside (1 to 8 µg/kg/min) in middle ear microsurgery operations. In a double blind clinical trial, sixty anesthetized patients allocate randomly in two groups and randomly take 10 minutes trials of different tidal volumes in normotension and hypotension states. Hemodynamic indices measure at the end of each trial of tidal volume and compare between two groups. A coworker prescribes hypotensive drugs and drugs remain blind to main researcher till end of study.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2014020516415N2**
Registration date: **2014-07-14, 1393/04/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2014-07-14, 1393/04/23

Registrant information
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Recruitment status
Recruitment complete

Funding source
Isfahan University of Medical Sciences

Expected recruitment start date
2014-02-20, 1392/12/01

Expected recruitment end date
2014-06-21, 1393/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative evaluation of effects of different tidal volumes of mechanical ventilation on hemodynamic indices during deliberate hypotension by using nitroprosside & nitroglycerine in ear microsurgery patients

Public title
Effects of different tidal volumes on hemodynamic indices during deliberate hypotension by using nitroprosside & nitroglycerin

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: ASA 1 and 2; non smokers; no cardiopulmonary and renal disease; candidates for elective middle ear microsurgery. Exclusion criteria: Bleeding more than 2cc/kg; bronchospasm during surgery; need to other hypotensive drugs other than drugs of study.

Age
No age limit
Gender
Both

Phase
2
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
Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezarjarib Boulevard, Isfahan, Iran
City
Isfahan
Postal code
Approval date
2002-07-16, 1381/04/25
Ethics committee reference number
81124

Health conditions studied

1

Description of health condition studied
Drug induced Hypotension
ICD-10 code
I95.2
ICD-10 code description
Hypotension due to drugs

Primary outcomes

1

Description
Heart rate, Blood pressure, Cardiac output, Stroke Volume
Timepoint
At the end of each tidal volume trial
Method of measurement
Measurement by anesthesia monitoring system and TECO (Trans Esophageal Cardiac Output measurement)

Secondary outcomes

1

Description
Peak airway pressure, Plateu airway pressure
Timepoint
At the end of each trial different tidal volumes
Method of measurement
By ventilator of anesthesia mashine

Intervention groups

1

Description
First group: changing tidal volume between 5, 10 and 15 ml/kg during infusion of nitroglycerin. Nitroglycerin infusees in 0.5 mic/kg after induction of anesthesia and increase till 30% decrease in mean blood pressure (target blood pressure) and then infusion speed changes to serve mean blood pressure within 20% of target blood pressure)
Category
Treatment - Drugs

2

Description
Second group: changing tidal volume between 5, 10 and 15 ml/kg during infusion of Na nitroprusside. Na Nitroprusside infusees in 1 mic/kg after induction of anesthesia and increase till 30% decrease in mean blood pressure (target blood pressure) and then infusion speed changes to serve mean blood pressure within 20% of target blood pressure).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Medical Center
Full name of responsible person
Golparvar M. MD
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Sponsors / Funding sources

1

Sponsor
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Research manager office, Deputy of research and technology, Isfahan University of Medical Sciences; Hezarjarib Boulevard, Isfahan, Iran
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Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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

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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