

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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

Name

Mohammad Golparvar

Name of organization / entity

Isfahan University of Medical Sciences

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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, Plateau airway pressure

Timepoint

At the end of each trial different tidal volumes

Method of measurement

By ventilator of anesthesia machine

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

First group: changing tidal volume between 5, 10 and 15 ml/kg during infusion of nitroglycerin. Nitroglycerin infuses 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 infuses 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

Street address

Department of Anesthesia, Alzahra Medical center,
Sofeh boulevard, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Ali M Sabzghabaee

Street address

Research manager office, Deputy of research and technology, Isfahan University of Medical Sciences; Hezarjarib Boulevard, Isfahan, Iran

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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

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

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Golparvar M MD

Position

Associate professor in Medical School of Isfahan University of Medical Sciences

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

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Person responsible for scientific inquiries

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Associate Professor of Anesthesia and Critical Care Group

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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