Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of continuous infusion of Nitroglycerin and Dobutamine on incidence and severity of Occult Hypoperfusion in Orthopedic Surgery's Patients who underwent General and Epidural Anesthesia

Protocol summary

Summary

Tissue Hypoperfusion is a condition of imbalance between oxygen delivery and consumption. It leads to tissue damage if persists, particularly in critically ill patients or during long surgeries. It is important to prevent vasoconstriction of microvessels preluding tissue hypoperfusion and injury.Objectives: This study aims to evaluate the effects of low-dose continuous vasodilator agents on patients susceptible to hypoperfusion damage. Design: This is a double-blind randomized controlled study of 56 patients undergoing long orthopedic surgery (more than 120 minutes).The patients divide randomly into two groups of 28 patients (receivers of nitroglyecerin - dubotamine and control); each group also randomizes to receive general and epidural anesthesia in two groups of 14 patients. inclusion criteria : Patient's satisfaction with participating in the study; Patients in group I and II ASA Score; No history of Liver or Renal insufficiency, DM, HTN, Heart and Pulmonary disease; No acid-base disorders; No TNG, dubotamine or anesthetic drugs allergy; No emergent surgery; No pregnancy; No contraindications of TNG(Idiopathic hypertrophic subaortic stenosis, post myocardial infarction hypertension); No contraindications of dubotamine(myocardial infarction, open angle glaucoma, allergy to phosphodiesterase inhibitors, cerebral hemorrhage, ICP rise, severe anemia, orthostatic hypotention, sildenafil use in restrictive cardiomyopathy) Exclusion Criteria: Resistant drop in blood pressure with mean arterial pressure less than 60; Increasing blood pressure needing therapeutic interventions more than predicted in study method. Setting and conduct: Treatments in intervention group includes trinitroglycerin 0.1 µg/kg/min and dobutamine 1.5-2 µg/kg/min during surgery. The control group receives standard anesthetic and analgesic techniques beside 100 cc normal saline as placebo. All the patients in operation room are under monitoring, NIBP, IBP, pulse oxymetry and pulse rate measuring.Arterial Blood Gas is checked in the start of anesthesia, per hour during surgery and at the end.Finally data is gathered and analyzed in SPSS and hypoperfusion markers such as pH, bicarbonate, base excess, pO2, pCO2 and oxygen saturation are compared in the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011815774N2**
Registration date: **2015-04-04, 1394/01/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-04, 1394/01/15

Registrant information

Name

Mohammad Mahdi Zamani

Name of organization / entity

Tehran University of Medical Sciences, Students' Scientific Research Center

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran university of medical sciences

Expected recruitment start date
2013-01-01, 1391/10/12
Expected recruitment end date
2015-01-01, 1393/10/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of continuous infusion of Nitroglycerin and Dobutamine on incidence and severity of Occult Hypoperfusion in Orthopedic Surgery’s Patients who underwent General and Epidural Anesthesia

Public title
The Effect of Continuous Infusion of Nitroglycerin and dobutamine on occult hypoperfusion in patients under anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria : Patient's satisfaction with participating in the study; Patients with group I and II ASA Score; No history of Liver or Renal insufficiency, DM, HTN, Heart and Pulmonary disease; No acid-base disorders; No TNG, dubotamine or anesthetic drugs allergy; No emergent surgery; No pregnancy; No contraindications of TNG(Idiopathic hypertrophic subaortic stenosis, post myocardial infarction hypertension); No contraindications of dubotamine(myocardial infarction, open angle glaucoma, allergy to phosphodiesterase inhibitors, cerebral hemorrhage, ICP rise, severe anemia, orthostatic hypotention, sildenafil use in restrictive cardiomyopathy). Exclusion Criteria: Resistant drop in blood pressure with mean arterial pressure less than 60; Increasing blood pressure needing therapeutic interventions more than predicted in study method.
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Commitee of Iran University of Medical Sciences
Street address
West Hemmat Highway
City
Tehran
Postal code
Approval date
2014-10-18, 1393/07/26
Ethics committee reference number
93/105/3332/ر

Health conditions studied

1

Description of health condition studied
metabolic acidosis
ICD-10 code
E87.2
ICD-10 code description
An abnormal increase in the acidity of the body's fluids

Primary outcomes

1

Description
serum bicarbonate concentration
Timepoint
Before start of anesthesia, per hour during surgery, at the end of surgery
Method of measurement
Arterial Blood Gas Analysis

2

Description
serum base deficit
Timepoint
Before start of anesthesia, per hour during surgery, at the end of surgery
Method of measurement
Arterial Blood Gas Analysis

Secondary outcomes

empty

Intervention groups

1

Description
Treatments in intervention group included trinitroglycerin 0.1 µg/kg/min and dobutamine 1.5-2 µg/kg/min during surgery
Category
Treatment - Drugs

2

Description
The control group received 100 cc normal saline as placebo during the surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Dr Mohammad Mahdi Zamani
Street address
Operation room, Firoozgar Hospital, Beh Afarin St., Karim Khan Zand Ave., Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran university of medical sciences
Full name of responsible person
Dr.Morteza Naserbakht
Street address
floor 5, central building, junction of Shahid Hemmat & Shahid Chamran Expressways, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Iran 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Anesthesiology, Iran University of Medical Sciences, Tehran, Iran
Full name of responsible person
Dr. Saeed Reza Entezari
Position
Assistant Professor/Attending Physician
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Web page address

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