Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison Between The Hemodynamic Effects of Cutaneous Nitroglycerin And Intravenous Nitrogltcerin In Patients Under Phacoemulsification surgery surgery

Protocol summary

Summary

The purpose of this study is comparison between the hemodynamic changes of skin patch of nitroglycerin and intravenous nitroglycerin in phacoemulsification surgery. This study is designed as a randomized, prospective, interventional and single blind clinical trial. The study population all the known ischemic heart patients who are candidate for phacoemulsification surgery. Inclusion criteria consist of: Phacoemulsification surgery under general anesthesia. Exclusion criteria consist of: Patients with uncontrolled type 1and type 2 diabetics ; Severe left ventricular dysfunction; patients with ASA 3 and more. In this study 50 patients are selected and 25 patients in one groups are considered. One group of patients will be received nitroglycerin skin patch up to 2 cm on the anterior chest wall 40 minutes before induction of anesthesia. Another group will be received 0.5 mcg / kg / min intravenous nitroglycerin before induction of anesthesia and the dose will be adjusted according to hemodynamic changes. Systolic blood pressure ;diastolic blood pressure; mean arterial blood pressure and heart rate will be recorded with noninvasive heart monitoring with a specified times (before induction of anesthesia ; 1 minute and 3 minutes after induction ; after placement of a laryngeal mask ; after surgical stimulation; after removal of laryngeal mask; 2 hours postoperative).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105125751N2**
Registration date: **2012-07-20, 1391/04/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-07-20, 1391/04/30

Registrant information

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical sciences

Expected recruitment start date

2012-07-24, 1391/05/03

Expected recruitment end date

2012-08-25, 1391/06/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Between The Hemodynamic Effects of Cutaneous Nitroglycerin And Intravenous Nitrogltcerin In Patients Under Phacoemulsification surgery surgery

Public title

Comparison of Two Different Forms of Nitroglycerin In Anesthesia of The Patients Under Phacoemulsification Surgery

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria consist of: Known Ischemic Heart Disease Patients Candidate for Phacoemulsification Surgery Exclusion criteria Consist of : Uncontrolled Type 1 and 2 Diabetics; Patients With Severe Left ventricular Dysfunction
Age
From **50 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Busheh University of Medical Sciences
Street address
Pardis Site; Bahmani; Bushehr University of Medical Sciences
City
Bushehr
Postal code
Approval date
2012-05-17, 1391/02/28
Ethics committee reference number
10581

Health conditions studied

1

Description of health condition studied
Cataract
ICD-10 code
H25.9
ICD-10 code description
Senile cataract, unspecified

Primary outcomes

1

Description
Systolic Blood Pressure
Timepoint
Before Induction of anesthesia; 1 minute after induction; 3 minutes after induction; after LMA insersion; after surgical stimulation; post extubation; 2 hours postoperation
Method of measurement
Noninvasive Blood Pressure Monitoring

2

Description
Diastolic Blood Pressure
Timepoint
Before induction of anesthesia; 1 minute after induction; 3 minutes after induction; after LMA insersion; after surgical stimulation; post extubation; 2 hours postoperation
Method of measurement
Noninvasive Blood Pressure Monitoring

3

Description
Heart Rate
Timepoint
Before induction of anesthesia; 1 minute after induction; 3 minutes after induction; after LMA insersion; after surgical stimulation; post extubation; 2 hours postoperation
Method of measurement
Noninvasive Blood Pressure Monitoring

4

Description
Mean Arterial Pressure
Timepoint
Before induction of anesthesia; 1 minute after induction; 3 minutes after induction; after LMA insersion; after surgical stimulation; post extubation; 2 hours postoperation
Method of measurement
Noninvasive Blood Pressure Monitoring

Secondary outcomes

1

Description
New Changes In Electrocardiography
Timepoint
Perioperative Period; 2 hours after operation
Method of measurement
Noninvasive Blood Pressure Monitoring

Intervention groups

1

Description
In Interventional Group: Skin Patch of Nitroglycerin up to 2 cm Anterior Chest Wall 40 minutes Before Induction of Anesthesia
Category
Treatment - Drugs

2

Description
In Control Group: Intravenous Nitroglycerin 0.5 microgram/kg/minute Before Induction of anesthesia
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemezahra Hospital
Full name of responsible person
Abdolrasoul anvaripour
Street address
Fatemezahra Hospital; Moalem Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bushehr Universiy of Medical Sciences
Full name of responsible person
Mahnoush khakzad
Street address
Pardis site; Bahmani
City
Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bushehr Universiy 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
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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