

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison Between The Hemodynamic Effects of Cutaneous Nitroglycerin And Intravenous Nitroglycerin 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 1 and 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

Name

Abdolrasoul Anvaripour

Name of organization / entity

Bushehr University of Medical Sciences

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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 Nitroglycerin 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

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bushehr University 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 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

Bushehr University of Medical Sciences

Full name of responsible person

Abdolrasoul Anvaripour

Position

Assistant Professor of Cardiac Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

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Other areas of specialty/work

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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