

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 77 1252 6801

###### Email address

anvari@bpums.ac.ir

##### 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

##### 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 insertion; 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 insertion; 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 insertion; 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 insertion; 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

##### Street address

Fatemezahra Hospital

##### City

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##### Postal code

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+7 712526802

##### Fax

##### Email

a.anvari.p@hotmail.com anvari@bpums.ac.ir

##### Web page address

## Person responsible for scientific 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

##### Street address

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Bushehr University of Medical Sciences

##### Full name of responsible person

Abdolrasoul Anvaripour

##### Position

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##### Street address

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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*