

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Pupillary Response to Nitrous Oxide Administration in Cataract Surgery under General Anesthesia

#### Protocol summary

##### Summary

Objective: To evaluate the effect of Nitrous Oxide on Pupillary diameter in cataract surgery under general anesthesia. Study design: randomized prospective, interventional, double blind clinical trial. Inclusion criteria: Forty patients with cataract 50 to 80 year- old; ASA 1 or 2. Exclusion criteria: patients with obesity (BMI >30); blood pressure above 160/90 mmHg; glaucoma, pseudo exfoliation pupillary adhesions; optical trauma; clear corneal opacity (Leucoma); diabetes and endotracheal intubation more than 30 seconds. Interventions: Forty patients with cataract, scheduled for operation under general anesthesia were randomly allocated in two groups. After induction of anesthesia, it was maintained with Isoflurane and nitrous oxide oxygen (60%-40%) in group "1" versus oxygen 100% in group "2". Pupillary diameter was measured by pupillometer (Colvard Pupillometer manufactured by OASIS, United States) and blood pressure and heart rate will be measure and recorded at 4 time points( before anesthesia induction, before endotracheal intubation, one and five minutes after intubation).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016071319470N34**  
Registration date: **2016-10-20, 1395/07/29**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-10-20, 1395/07/29

##### Registrant information

Name

Farzaneh Masihi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

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**Email address**

masihif@sums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice Chancellor for Research, Shiraz University of Medical Sciences

**Expected recruitment start date**

2013-03-10, 1391/12/20

**Expected recruitment end date**

2013-09-11, 1392/06/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Pupillary Response to Nitrous Oxide Administration in Cataract Surgery under General Anesthesia

**Public title**

Pupillary Response to Nitrous Oxide Administration in Cataract Surgery

**Purpose**

Diagnostic

**Inclusion/Exclusion criteria**

Inclusion criteria: Forty patients with cataract 50 to 80 year- old; ASA 1 or 2. Exclusion criteria: patients with obesity (BMI >30); blood pressure above 160/90 mmHg; glaucoma, pseudo exfoliation pupillary adhesions; optical trauma; clear corneal opacity (Leucoma); diabetes and endotracheal intubation more than 30 seconds

## Age

From **50 years** old to **80 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Vice Chancellor of research, Shiaz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

##### City

Shiraz

##### Postal code

#### Approval date

2010-08-20, 1389/05/29

#### Ethics committee reference number

CT-P-91-5274

## Health conditions studied

### 1

#### Description of health condition studied

Cataract

#### ICD-10 code

H25.0

#### ICD-10 code description

Senile incipient cataract

## Primary outcomes

### 1

#### Description

Pupillary diameter measurment

#### Timepoint

before anesthesia induction, before endotracheal intubation, one and five minutes after intubation

#### Method of measurement

by pupillometer (Colvard Pupillometer manufactured by OASIS, United States)

## Secondary outcomes

### 1

#### Description

blood pressure

#### Timepoint

before anesthesia induction, before endotracheal intubation, one and five minutes after intubation

#### Method of measurement

Sphygmomanometer

### 2

#### Description

heart rate

#### Timepoint

before anesthesia induction, before endotracheal intubation, one and five minutes after intubation

#### Method of measurement

pulsoximeter

## Intervention groups

### 1

#### Description

Intervention group: After induction of anesthesia, anesthesia is maintained with Isoflurane and nitrous oxide oxygen (60%-40%) in intervention group.

#### Category

Diagnosis

### 2

#### Description

Control group: After induction of anesthesia oxygen 100% was administered in control group.

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khalili Hospital

##### Full name of responsible person

Mnsoor Masjedi

##### Street address

Khalili Hospital, Khalili Street  
**City**  
Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Seed Basir Hashemi

**Street address**

Vice chancellor of research, 7th floor of central  
building of Shiraz University of Medical Sciences  
, Zand street

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Alireza GhANBARI

**Position**

Anesthesia Nurse

**Other areas of specialty/work**

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand  
Street

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University Of Medical Sciences

**Full name of responsible person**

Dr Mansoor Masjedi

**Position**

Anesthesiologist, ICU fellow ship

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz anesthesiology and critical care research  
center

**Full name of responsible person**

Farzaneh Masihi

**Position**

English Consultant

**Other areas of specialty/work**

**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*

