

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparison of the effects of Dexmedetomidine and Remifentanyl sedation on cognition in mustard gas veterans under cataract surgery

#### Protocol summary

##### Summary

Goal: Comparing of the effects of Dexmedetomidine and Remifentanyl sedation on cognition in mustard gas veterans under cataract surgery. Objectives: 1- Determine and comparing Heart rate in the two groups 2- Determine and comparing Blood pressure in the two groups 3- Determine and comparing SPO2 in the two groups 4- Determine and comparing Cognition state in the two groups A double blind randomized clinical trial study in Labbafinejad hospital on 100 mustard gas veterans who are candidate for topical cataract surgery. The Inclusion criteria are Inclusion criteria: Age between 40 to 70 years old; ASA Class I&II; Mustard gas veterans under topical cataract surgery Exclusion criteria: Nausea and Vomiting more than 3times; Surgery time more than 120min; Any problem with the medicine protocol; initial MMSE score less than 23; Heart rate less than 45 Sample: 100 Patients Intervention: Group #1: Dexmedetomidine (0.5µg/kg) as a bolus dose in 10 minutes slowly and 5 minutes before topical anesthesia. The infusion dose was administered by 0.2 µg/kg/hr. Group #2: Remifentanil (0.1µg/kg) as a bolus dose in 10 minutes slowly and 5 minutes before topical anesthesia. The infusion dose was administered 0.05 µg/kg/min. Finally, we will compare the effects of Dexmedetomidine and Remifentanil on HR, BP, SPO2 and Cognition state.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012082710678N1**  
Registration date: **2016-02-01, 1394/11/12**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-02-01, 1394/11/12

##### Registrant information

###### Name

Mahtab Poor zamany nejat kermany

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2254 9029

###### Email address

drmpoorzamani@sbm.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice-Chancellor in Research Affairs of Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2015-03-21, 1394/01/01

##### Expected recruitment end date

2016-03-19, 1394/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effects of Dexmedetomidine and Remifentanyl sedation on cognition in mustard gas veterans under cataract surgery

##### Public title

effects of Dexmedetomidine and Remifentanyl sedation on cognition

##### Purpose

Diagnostic

## Inclusion/Exclusion criteria

Inclusion criteria: Age between 40 to 70 years old; ASA Class I&II; Mustard gas veterans under topical cataract surgery  
Exclusion criteria: Nausea and Vomiting more than 3times; Surgery time more than 120min; Any problem with the medicine protocol; initial MMSE score less than 23; Heart rate less than 45

### Age

From **40 years** old to **70 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **100**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice- Chancellor in Research Affairs, Shahid Beheshti  
University of Medical Sciences

##### Street address

7th Floor , 2nd SBUMS Bldg. ,Next to Ayatollah  
Taleghani Hospital, Evin

##### City

Tehran

##### Postal code

198396-3113

#### Approval date

2014-11-15, 1393/08/24

#### Ethics committee reference number

sbmu.rec.1393.348

## Health conditions studied

### 1

#### Description of health condition studied

cognition

#### ICD-10 code

R41

## ICD-10 code description

Other symptoms and signs involving cognitive functions  
and awareness

## Primary outcomes

### 1

#### Description

Heart rate

#### Timepoint

Just before injection the anesthetic agents then every 5  
minutes during the surgery

#### Method of measurement

ECG Monitoring

### 2

#### Description

Blood pressure

#### Timepoint

Just before injection the anesthetic agents then every 5  
minutes during the surgery

#### Method of measurement

non invasive blood pressure monitoring

### 3

#### Description

SPO2

#### Timepoint

Just before injection the anesthetic agents then every 5  
minutes during the surgery

#### Method of measurement

Pulse oximetry

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention: Dexmedetomidine (0.5µg/kg) as an IV,  
bolus dose in 10 minutes slowly and 5 minutes before  
starting the topical anesthesia. The infusion dose will  
administer by 0.2 µg/kg/hr for maintenance during the  
surgery

#### Category

Diagnosis

### 2

#### Description

Control: Remifentanyl (0.1µg/kg) as a bolus dose in 10  
minutes slowly and 5 minutes before topical anesthesia.  
The infusion dose will administer 0.05 µg/kg/min for  
maintenance during the surgery.

#### Category

Diagnosis

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Labbafinejad Hospital

**Full name of responsible person**

Mahtab Poor Zamany Nejat Kermany

**Street address**

9th Boostan, Pasdaran Ave

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice- Chancellor in Research Affairs, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi, PhD

**Street address**

7th Floor , 2nd SBUMS Bldg. ,Next to Ayatollah Taleghani Hospital, Evin

**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 in Research Affairs, Shahid Beheshti 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**

Faculty Member of Shaheed Beheshti University of Medical science

**Full name of responsible person**

Mahtab Poor Zamany Nejat Kermany

**Position**

Anesthesiologist

**Other areas of specialty/work****Street address**

9th Boostan, Pasdaran Ave

**City**

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**Postal code**

1666694516

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drmpoorzamani@sbm.ac.ir,

drpoorzamani@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Faculty Member of Shaheed Beheshti University of Medical science

**Full name of responsible person**

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## Person responsible for updating data

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drpoorzamani@yahoo.com

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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*