

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

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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

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Web page address

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