Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparation of sedation sufentanil and midazolam with nitrous oxide in patients of cataract surgery

Protocol summary

Summary

The present study aims to compare the sedation effects of Sufentanil and midazolam with nitrous oxide during cataract surgery. It is a double blind clinical study. 100 patients attending Imam Khomainy hospital in Kermanshah were candidate to have cataract surgery who were divided to control and experiment group randomly. The experiment group received a mixture of %33 nitrous oxide and %66 oxygen in Face ratio with flow of 6 lit/min. Extra gas and patient's expiration were vacuumed using a mask which was linked to the air conditioning system. After 3 to 5 minutes after gas emission, members of the control group were under surgery using regional anesthesia perry bulbar. 5 Milligram of sufentanil (common treatment) was indoctrinated with oxygen and air in ratio of %50 in a flow of 6 liters in minute in %50 and patients were operated using regional anesthesia perry bulbar and infusion face mask 100 to 500 milliliter liquid. Both groups were examined for their blood pressure heart rate, vein blood oxygen saturation before the surgery, beginning the surgery and throughout the surgery every 5 minutes. They were also checked before transferring the patient to recovery room. Inclusion: satisfaction of patients; candidates to cataract surgery; Exclusion: people under 18 or over 80; pregnant women; patients with chronic lung diseases; heart failure with chronic hypoxemia; addicts; patients who experienced general anesthesia or surgeries longer than 30 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011314333N28**
Registration date: **2015-01-31, 1393/11/11**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-01-31, 1393/11/11

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Kermanshah university of medical sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparation of sedation sufentanil and midazolam with nitrous oxide in patients of cataract surgery

Public title

Comparison of sedation effects of sufentanil and midazolam with nitrous oxide in cataract surgery

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion: satisfaction of patients; candidates to cataract surgery; Exclusion: people under 18 or over 80; pregnant women; patients with chronic lung diseases; heart failure with chronic hypoxemia; addicts; patients who experienced general anesthesia or surgeries longer than 30 minutes.
Age
From **18 years** old to **80 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
Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Approval date
2014-03-04, 1392/12/13
Ethics committee reference number
420/7/3959/پ

Health conditions studied

1

Description of health condition studied
cataract surgery
ICD-10 code
H43.9
ICD-10 code description
Disorder of vitreous body, unspecified

Primary outcomes

1

Description
Blood pressure
Timepoint
Every 5 minutes before the surgery, beginning the surgery and during the surgery; after the surgery and before transferring the patient to recovery room
Method of measurement
Recording blood pressure with monitoring tools

2

Description
Heart beat
Timepoint
Every 5 minutes before the surgery, beginning the surgery and during the surgery; after the surgery and before transferring the patient to recovery room
Method of measurement
The number of heart beats recorded by monitoring tool

3

Description
Vain blood oxygen saturation
Timepoint
Every 5 minutes before the surgery, beginning the surgery and during the surgery; after the surgery and before transferring the patient to recovery room
Method of measurement
Based on ratio of vein blood oxygen saturation recorded by monitoring and pulse oximetry tools

4

Description
Patient movement
Timepoint
Beginning the surgery and every 5 minutes to the end of the surgery
Method of measurement
By the doctor

Secondary outcomes

empty

Intervention groups

1

Description
The experiment group received a mixture of nitrous oxide (aspiration gas with oxygen made in Iran Darman Gaz) and oxygen company with ratio of %66 and %33 in Face mask with flow of 6 lit/min while it is fixed on the patient’s face. Extra gas and patient’s expiration were vacuumed through the mask which was linked to the air

conditioning system. After 3 to 5 minutes after gas emission, operation is accomplished using regional anesthesia perry bulbar. Patients were examined for their blood pressure heart rate, vein blood oxygen saturation before the surgery, beginning the surgery and throughout the surgery every 5 minutes. They were also checked before transferring the patient to recovery room.

Category

Treatment - Drugs

2

Description

The experiment group received 5 Milligram of sufentanil (common treatment) (the injection of mic/ml made of Teharan Daroopakhsh company-Iran) and 1 milligram of IV midazolam 5 mg/ml (produced by Teharn daroopakhsh company-Iran) were indoctrinated with oxygen and air in ratio of %50 in a flow of 6 liters in minute in %50. Face with 100 to 500 milliliter liquid was used and patients went under operation using regional anesthesia perry bulbar. Then, patients were examined for their blood pressure heart rate, vein blood oxygen saturation before the surgery, beginning the surgery and throughout the surgery every 5 minutes. They were also checked before transferring the patient to recovery room.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeyni hospital

Full name of responsible person

Dr. Ali Gholami

Street address

Emam Khomeyni hospital, Street of Naghliyeh

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Bahman Roshani

Position

Anesthesiologists

Other areas of specialty/work

Street address

Emam Khomeyni hospital, Street of Naghliyeh

City

Kermanshah

Postal code

Phone

+98 83 3728 5054

Fax

Email

Broshani@yahoo.com

Web page address

Person responsible for updating data

Contact

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*