Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of supplemental oxygen during the procedure on postoperative nausea and vomiting in patients undergoing cataract surgery

Protocol summary

Summary

Aim:Compare the frequency of postoperative nausea and vomiting (PONV) in patients undergoing cataract surgery in two groups :receiving 30% and 80% of oxygen during the operation.This is a double-blind randomized clinical trial without control of placebo,with inclusion criteria:All patients 40-70 years old ; ASA(American Society of Anesthesiologists) Class 1,2 and exclusion criteria: history of postoperative nausea and vomiting; motion sickness; obesity; pregnancy; breastfeeding; smoking; use of antiemetic drugs within 24 hours prior to surgery; migrain headache; duration of surgery more than an houre; diabetes melitus.In this study two hundred patients candidate for cataract surgery(Under general anesthesia) were randomly divided into two groups: group A(The recipient of 30 percent oxygen) and group B (The recipient of 80 percent supplemental oxygen).We compared the frequency of nausea and vomiting after surgery and its incidence in the two groups discussed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020126300N1**
Registration date: **2016-09-07, 1395/06/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-07, 1395/06/17

Registrant information

Name

Mahshid Ashrafzadeh

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supplemental oxygen during the procedure on postoperative nausea and vomiting in patients undergoing cataract surgery

Public title

The effect of oxygen on nausea and vomiting

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:All patients 40-70 years old; ASA(American Society of Anesthesiologists) Class 1,2
Exclusion criteria:History of postoperative nausea and vomiting; motion sickness; obesity; pregnancy; breastfeeding; smoking; use of antiemetic drugs within 24 hours prior to surgery; migrain headache; duration of the surgery more than one houre; diabetes melitus.

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: **200**
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
Zahedan University of Medical Sciences
Street address
Zahedan University of Medical Sciences,Doctor Hesabi Sq.
City
Zahedan
Postal code
9816743463
Approval date
2015-08-02, 1394/05/11
Ethics committee reference number
IR.zaums.rbc.1394.196

Health conditions studied

1

Description of health condition studied
postoperative nausea and vomiting
ICD-10 code
k91.9
ICD-10 code description
Postprocedural disorder of digestive system, unspecified

2

Description of health condition studied
cataract
ICD-10 code
H26.9
ICD-10 code description
cataract,unspecified

Primary outcomes

1

Description
Nausea and vomiting
Timepoint
during the first 6 hours after surgery
Method of measurement
Observation and assessment with statistical methods

Secondary outcomes

empty

Intervention groups

1

Description
Group A: Receiving 30 percent oxygen during surgery
Category
Treatment - Other

2

Description
Group B: Receiving 80 percent oxygen during surgery
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Subspecialty Ophthalmology Hospital
Full name of responsible person
Mahshid Ashrafzadeh
Street address
Shahid Motahhari Boulevard,Azadi squar
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellery for Research and Information Technology,Zahedan University of Medical Sciences
Full name of responsible person
Doctor Rafighdoost Hooshang
Street address
Zahedan University of Medical Sciences,Doctor Hesabi sq.
City
Zahedan
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellery for Research and Information Technology,Zahedan 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
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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