Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

Evaluating the effects of oral dextromethorphan in acute pain after surgery in patients undergoing vitrectomy

Protocol summary

Summary

Postoperative pain management is an important part of postoperative care and plays an important role in postsurgical ambulation and general status of patients. We aim to evaluate the analgesic and sedative effects of preoperative oral dextromethorphan on post operation pain in patients undergoing vitrectomy. In this study, 60 patientsbetween 35 and 75 years old candidate for vitrectomy with ASA class I and II will be randomly assigned to two groups of 30 patients using random blocks. Patients and the person evaluating the outcome would be unaware of the given drug. The exclusion criteria include obese patients, History of opioid consumption within 48 hours of surgery and sedatives or centrally acting drugs 21 days prior to surgery, those with a history of chronic pain, psychotic disorders or addiction including opioids, those with any contraindications to dextromethorphan, and pregnant or lactating women. Before operation, patients will be administered 30 mg dextromethorphan or placebo orally. Pain severity and sedative level will be evaluated immediately after, 1, 2 and 6 hours post surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102510599N21**
Registration date: **2017-11-12, 1396/08/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-12, 1396/08/21

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9059

Email address

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor of research Iran University of Medical Sciences

Expected recruitment start date

2017-11-11, 1396/08/20

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of oral dextromethorphan in acute pain after surgery in patients undergoing vitrectomy

Public title

Evaluating the effects of oral dextromethorphan in acute pain after surgery in patients undergoing vitrectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients between 35 to 75 years old; with ASA classes I and II; undergoing vitrectomy under general anesthesia; Exclusion criteria: Obese patients; History of opioid consumption within 48 hours of surgery; sedatives or centrally acting drugs use (central nervous

system depressants or antidepressants) 21 days prior to surgery; those with a history of chronic pain; psychotic disorders or addiction including opioids; those with any contraindications to dextromethorphan; and pregnant or lactating women.

Age
From **35 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemmat high way

City
Tehran

Postal code
1449614535

Approval date
2016-06-01, 1395/03/12

Ethics committee reference number
IR.IUMS.REC.1395.9211184016

Health conditions studied

1

Description of health condition studied
Disorders of vitreous body

ICD-10 code
H43

ICD-10 code description
Disorders of vitreous body

2

Description of health condition studied
postprocedural pain

ICD-10 code
G89.18

ICD-10 code description
Pain during the period after surgery.

Primary outcomes

1

Description
pain

Timepoint
after surgery in recovery, 1, 2 and 6 hours after surgery

Method of measurement
using visual analogue scale

Secondary outcomes

1

Description
sedation rate

Timepoint
after surgery in recovery, 1, 2 and 6 hours after surgery

Method of measurement
using Ramsy sedation assessment scale

Intervention groups

1

Description
Patients in second group will receive placebo before induction and then undergo general anesthesia

Category
Placebo

2

Description
Patients in group one will receive 30 mg dextromethorphan orally before induction and then undergo general anesthesia

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool Akram Hospital

Full name of responsible person
Poopak Rahimzadeh

Street address
Rasool Akram Hospital, Mansouri St., Niyayesh Ave., Satarkhan St.

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor of research Iran University of Medical Sciences
Full name of responsible person
Dr. Seyyed Ali Javad Mousavi
Street address
Central staff, Iran University of Medical Sciences, Hemmat Highway
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 of research Iran 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
Rasool Akram Hospital
Full name of responsible person
Poopak Rahimzadeh
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Person responsible for scientific inquiries

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Person responsible for updating data

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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