

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluating the effects of oral dexamethorphan 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 dexamethorphan on post operation pain in patients undergoing vitrectomy. In this study, 60 patients between 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 dexamethorphan, and pregnant or lactating women. Before operation, patients will be administered 30 mg dexamethorphan 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

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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 dexamethorphan in acute pain after surgery in patients undergoing vitrectomy

Public title

Evaluating the effects of oral dexamethorphan 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 committee 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

Poupak Rahimzadeh

Position

Anesthesiologist

Other areas of specialty/work

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Position

Associate Prof of Anesthesia

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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