

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Postoperative Anxiolytic and Analgesic Effects of Pregabalin in Vitreo-Retinal Surgery: A randomized double-blind study

Protocol summary

Study aim

To examine the effect of a single one-time pregabalin dose on post-operative pain, anxiety and analgesic consumption after vitrectomy performed under peribulbar block

Design

Patients was randomly divided into 2 groups. The groups are parallel. The trial phase is 2-3

Settings and conduct

Candidates for vitreo-retinal surgery in Magrabi Eye, ENT and Dental Center, Doha, Qatar are divided into 2 groups. The groups are parallel. The trial phase is 2-3.

Participants/Inclusion and exclusion criteria

Exclusion criteria were; patients 'refusal to regional anesthesia, patients more than 75 years old, pregnancy, breast-feeding women, bleeding tendency, history of drug abuse, renal insufficiency, neurological or psychiatric disorders, or allergy to the study medication, intake of narcotic analgesics, pregabalin or benzodiazepines, within 24hrs before the study. Patients aged 18 and older who consented to participate in this study and who do not have exclusion criteria were included in our study

Intervention groups

A total of 58 patients were involved in this study. The pregabalin group composed of 30 cases who received pregabalin 150 mg as premedication and the placebo group involved 28 patients who received placebo.

Main outcome variables

Post-operative pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210117050057N1**

Registration date: **2021-01-26, 1399/11/07**

Registration timing: **prospective**

Last update: **2021-01-26, 1399/11/07**

Update count: **0**

Registration date

2021-01-26, 1399/11/07

Registrant information

Name

Mohamed Oriby

Name of organization / entity

Faculty of Medicine, Tanta University

Country

Egypt

Phone

+20 3 3059056

Email address

orai500@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-01, 1399/11/13

Expected recruitment end date

2021-04-01, 1400/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Postoperative Anxiolytic and Analgesic Effects of Pregabalin in Vitreo-Retinal Surgery: A randomized double-blind study

Public title

Postoperative Anxiolytic and Analgesic Effects of Pregabalin in Vitreo-Retinal Surgery: A randomized double-blind study

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 and older Consented to participate in this study
Exclusion criteria:
Patients' refusal to regional anesthesia Patients more than 75 years old Pregnancy Breast-feeding women Bleeding tendency History of drug abuse Renal insufficiency Neurological or psychiatric disorders or allergy to the study medication Intake of narcotic analgesics, pregabalin or benzodiazepines, within 24hrs before the study

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Independent technician was responsible for computer-generated codes to be able to obtain complete randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
These codes were kept in sealed envelopes which are sequentially numbered and opaque. A nurse who was not involved in the study opened these envelopes immediately before administration

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board (IRB) of Magrabi Eye & ENT Center

Street address

D ring road

City

Doha

Postal code

23293

Approval date

2021-01-02, 1399/10/13

Ethics committee reference number

MEEC-IRB- 2021-101

Health conditions studied

1

Description of health condition studied

Vitreo-Retinal surgery

ICD-10 code

H33

ICD-10 code description

Elective retinal surgeries

Primary outcomes

1

Description

Postoperative Pain

Timepoint

Postoperatively

Method of measurement

Verbal analogue pain score (VAS)

Secondary outcomes

1

Description

Anxiety

Timepoint

Postoperatively

Method of measurement

Verbal anxiety score

2

Description

Analgesic consumption

Timepoint

Postoperatively

Method of measurement

Calculation of analgesics consumed

Intervention groups

1

Description

Control group: Controlled (Placebo) group involved 28 patients who received placebo drugs as premedication

Category

Treatment - Drugs

2

Description

Intervention group: Case (Pregabalin) group involved 30 patients who received Pregabalin capsule 150 mg as premedication

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Magrabi Eye, ENT and Dental Center, Doha, Qatar

Full name of responsible person

MOHAMED ORIBY

Street address

D ring road

City

Doha

Postal code

23293

Phone

+974 4437 5046

Email

oraiby500@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Magrabi Eye, ENT and Dental Center, Doha, Qatar

Full name of responsible person

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Phone

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Email

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Magrabi Eye, ENT and Dental Center, Doha, Qatar

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Medicine, Tanta University

Full name of responsible person

MOHAMED ORIBY

Position

Lecturer of Anesthesiology

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available