

# 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**

Magrabi Eye, ENT and Dental Center, Doha, Qatar

**Street address**

D ring road

**City**

Doha

**Postal code**

23293

**Phone**

+974 4437 5046

**Email**

oraiby500@hotmail.com

**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**

Anesthesiology

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Tanta

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**Postal code**

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**Phone**

+20 3 3059056

**Email**

oraiby500@hotmail.com

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**Contact**

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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