Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation of post operative pain and stress after cataract surgery after gabapentin pretreatment: a single-blind clinical trial

Protocol summary

Study aim

Evaluation of post operative pain and stress after cataract surgery after gabapentin pretreatment

Design

In this single-blind clinical trial, 44 patients who underwent cataract surgery will be included. The control and intervention groups will consist of 22 patients each, who will be categorized by simple randomization and drawing.

Settings and conduct

The study will be carried out in the ophthalmology ward of Imam Khomeini Hospital in Urmia. One hundred minutes before topical anesthesia, patients in the intervention group will be given two 300 mg gabapentin capsules and patients in the control group will be given two similar capsules containing placebo for oral administration.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age between 18 to 75 years 2- Class 1 and 2 patients based on American society of Anesthesiologist (ASA) Classification (Class 1 includes individuals without underlying disease and Class 2 includes individuals with mild underlying disease) 3- Cataract surgery 4- consent to participate in the study Exclusion criteria: 1- Emergency surgery 2- Gabapentin allergy 3- BMI above 35 4- psychology disorders 5- Autoimmune disorders 6- using Warfarin 7- opium or alcohol abuse 8- Diabetes Mellitus 9- History of malignancy and Tumor resection.

Intervention groups

The intervention group received 600 mg of gabapentin 100 minutes before topical anesthesia and the placebo group received the same capsule containing placebo at the same time.

Main outcome variables

Post operative pain and stress severity after cataract surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211216053424N1**
Registration date: **2022-05-14, 1401/02/24**
Registration timing: **prospective**

Last update: **2022-05-14, 1401/02/24**
Update count: **0**

Registration date

2022-05-14, 1401/02/24

Registrant information

Name

Parvin Khaleghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 4234 0827

Email address

pkhaleghi1995@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of post operative pain and stress after cataract surgery after gabapentin pretreatment: a single-blind clinical trial

Public title

Evaluation of post operative pain and stress after cataract surgery after gabapentin pretreatment: a single-blind clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 75 years Class 1 and 2 patients based on American society of Anesthesiologist (ASA) Classification (Class 1 includes individuals without underlying disease and Class 2 includes individuals with mild underlying disease) Cataract surgery consent to participate in the study

Exclusion criteria:

Emergency surgeries Allergic reaction to Gabapentin BMI more than 35 kg/m2 Psychologic disorders Autoimmune disorders Diabetes mellitus Warfarin use Opium or alcohol addiction History of Malignancy and tumor resection surgery

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, drawing will be performed for simple randomization. Before starting the study, drawing will be performed for numbers among 1 to 44 and the first 22 drew numbers will consider as intervention group and other numbers will consider as control group. Then, after starting the study, numbers 1 to 44 will been dedicated to patients in order of their admission time.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to blinding, by cooperating with a Gabapentin producer company, 88 capsules which are exactly similar, including 44 capsules contains 300 mg Gabapentin and 44 capsules contains same amount of placebo will be bought. Then 100 minutes before topical anesthesia, by considering the intervention or control group, nurse or researcher will give two placebo or Gabapentin capsules for oral consuming to each patients

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

UMSU Central Site: Orjhans Street, Resalat Blvd, Urmia , Iran

City

Urmia

Province

West Azarbaijan

Postal code

571478334

Approval date

2021-11-10, 1400/08/19

Ethics committee reference number

IR.UMSU.REC.1400.307

Health conditions studied

1

Description of health condition studied

Cataract Surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of gabapentin pretreatment on pain severity based on Visual analogue Scale

Timepoint

15 minutes before surgery, when discharge from recovery, 12 hours and 24 hours after surgery

Method of measurement

Visual analogue Scale

Secondary outcomes

1

Description

Evaluation of the effect of gabapentin pretreatment on stress level based on GAD-7 after's cataract surgery

Timepoint

15 minutes before surgery, at the time of discharge from recovery, 12 hours and 24 hours after surgery

Method of measurement

General Anxiety Disorder Assessment (GAD-7)

Intervention groups

1

Description
Intervention group: Gabapentin 600 mg in the form of two 300 mg capsules will be taken orally 100 minutes before topical anesthesia.
Category
Treatment - Drugs

2

Description
Control group: Two capsules very similar to gabapentin capsules containing the same amount of placebo will be taken orally 100 minutes before topical anesthesia.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ophthalmology ward of Urmia Imam Khomeini university Hospital
Full name of responsible person
Reza Soudi
Street address
Imam Khomeini university Hospital, Ershad Ave, Modarres Blvd, Urmia, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Saber Gholizadeh
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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
Oroumia University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
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Reza Soudi
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
The demographic data can be accessible after the publication of the results also by consideration of maintaining the ethical principles and in accordance with the rules.
When the data will become available and for how long
Access to information is possible one year after the publication of the results
To whom data/document is available
The information will be available to the academic researcher
Under which criteria data/document could be used
The academic researcher can access the results by electronic E-mailing with the co-responder author of the study. Their request should be clear and in line with legal and ethical standards and only for further studies or statistical analysis.
From where data/document is obtainable
co-responding author
What processes are involved for a request to access data/document
By official or academic email
Comments