

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparative study in The effect of single dose pregabalin in reducing postoperative pain following photo refractive keratectomy (PRK)

Protocol summary

Summary

In a randomized double blind clinical trial to study on number 80 patients with ASA class I And II scheduled for elective PRK surgery .inclusion criteria for patient consent to perform PRK and consent to participate in the study. Exclusion criteria included corneal injuries and allergic to medicine and unwillingness to participate in the study. 30 minutes before surgery one group take 50 mg pregabalin PO and other group take placebo tablet with a glass of water .Patients undergoing surgery by a surgeon and a Method photo refractive keratectomy (PRK). At the end of surgery before discharge, 6 h, 12 h, 48 h and 72 h after surgery, the patients' pain using a visual index of pain (VAS) visual analogue scale is measured and recorded. The results are under analysis and review

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109231617N5**
Registration date: **2012-05-21, 1391/03/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-05-21, 1391/03/01

Registrant information

Name

Mansour Choubsaz

Name of organization / entity

Imam Reza Hospital

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences and health Services

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study in The effect of single dose pregabalin in reducing postoperative pain following photo refractive keratectomy (PRK)

Public title

The effect of single dose pregabalin in reducing postoperative pain following photo refractive keratectomy (PRK)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria for patient consent to perform PRK and consent to participate in the study. Exclusion criteria included corneal injuries and allergic to medicine and unwillingness to participate in the study

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Kermanshah University of Medical Sciences

Street address

Pro-Vice-Chancellor for Research, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2012-02-05, 1390/11/16

Ethics committee reference number

61015

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

H57.1

ICD-10 code description

Ocular pain

Primary outcomes

1

Description

Pain

Timepoint

72 hours after discharge

Method of measurement

Visual analogue score

Secondary outcomes

1

Description

Analgesic use

Timepoint

72 hours after discharge

Method of measurement

Calculating dosage

Intervention groups

1

Description

Pregabalin 50 mg oral tablet with a glass of water 30 minutes before surgery

Category

Prevention

2

Description

Placebo oral tablet with a glass of water 30 minutes before surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr. Farid Najafi

Street address

Pro-Vice-chancellor for research, Kermanshah University of Medical Sciences

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences and health Services

Full name of responsible person

Mohamad Reza Nikbakhat

Street address

Kermanshah University of Medical Sciences and health Services

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Kermanshah

Grant name

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences and health Services

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**

Imam Reza Hospital

Full name of responsible person

Tayebeh kazerooni

Position

Resident of Anesthesiology

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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*