

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the analgesic effect of Pregabalin in post Dacryo Cysto Rhinostomy (DCR) Pain Management

Protocol summary

Vice Chancellor for research, Tehran University of Medical Sciences

Summary

In this double blind randomized clinical trail, 80 patinets 18-60 ASA1-2 who scaduled for Dacryo Cysto Rhinostomy in Rasul-e-Akram hospital were enrolled and assigned in two pregabalin and placebo groups randomly. Patients in pregabalin group had taken oral pregabalin (300) mg one hour pre surgical procedure, the others received placebo. Pain level and incidence of nausea and vomiting were compared between two groups at 4, 8, 12, 16, 20 and 24 hours after surgery.

Expected recruitment start date

2010-03-11, 1388/12/20

Expected recruitment end date

2011-07-11, 1390/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102185857N1**

Registration date: **2012-01-21, 1390/11/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-01-21, 1390/11/01

Registrant information

Name

Mahzad Alimian

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8868 0158

Email address

m-alimian@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Scientific title

Evaluation of the analgesic effect of Pregabalin in post Dacryo Cysto Rhinostomy (DCR) Pain Management

Public title

Evaluation of the analgesic effect of Pregabalin in post surgery patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-age between 18-60 2-candidated for surgery 3-signing informed consent to enter to this study. Exclusion criteria: 1-history of Hypertension- Diabet Mellitus- Ischemic heart disease- Renal and hepatic disease 2-Addiction 3-ASA or NSAIDS users for a long time

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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 Tehran University of Medical Sciences

Street address

Hemat high way, Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2010-02-21, 1388/12/02

Ethics committee reference number

989پ

Health conditions studied

1

Description of health condition studied

General anesthesia

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Pain mesasured by VAS

Timepoint

At recovery, then 30 min, 2, 4, 12, 24 hours after the surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Nausia and vomiting rate

Timepoint

in the recovery 30 min- 2-4-12-24 hours after the surgery

Method of measurement

asking from the patient

Intervention groups

1

Description

Patients in pregabalin group had taken oral pregabalin (300) mg one hour before surgery

Category

Treatment - Drugs

2

Description

Placebo group received placebo capsules filled with vitamime C

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasul-e-Akram Hospital

Full name of responsible person

Mahshid Sharifian (resident of anesthesiology)

Street address

Rasul-e-Akram Hospital, Niayesh st., Satarkhan Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Miss Irani

Street address

Central building, Tehran University of Medical Sciences, Ghods Street, Keshavarz blv., Tehran

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 for research, Tehran 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

tehran medical university

Full name of responsible person

Mahzad alimlan

Position

anesthesiologist

Other areas of specialty/work

Street address

rasule akram hospital

City

tehran

Postal code

Phone

+98 21 6435 2326

Fax

Email

m-alimian@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran university of Medical science

Full name of responsible person

Mahzad Alimian

Position

Anesthesiologist

Other areas of specialty/work

Street address

Rasool-Akram hospital - niayesh st.- satarkhan Ave.

City

Tehran

Postal code

Phone

+98 21 6435 2326

Fax

Email

m-alimian@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran university of medical science

Full name of responsible person

Mahshid Sharifian

Position

Anesthesiology Resident

Other areas of specialty/work

Street address

Rasule Akram Hospital

City

Tehran

Postal code

Phone

+98 21 6435 2326

Fax

Email

dr.msharifian@yahoo.com

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