

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the effectiveness of pregabalin and placebo on post thyroidectomy pain of patients with thyroid carcinoma

Protocol summary

Study aim

Determining the effect of pregabalin drug on postoperative pain after thyroidectomy

Design

Clinical trial with control group, with parallel groups, double blind, randomized phase 2 on 30 patients. The envelope method will be used for randomization.

Settings and conduct

The study will be conducted in the ear, throat and nose department of Hamadan Besat Hospital. Patients will be selected through convenience and consecutive method and randomly assigned to intervention and control groups. In this study, pregabalin and placebo capsules will be prepared in the same form with separate code. The person who will prescribe the medicine and the person who will measure the outcome of the intervention will be unaware of the treatment groups until the results are analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: candidate for thyroidectomy; being at the age of 20 to 60 years; weighing 40 to 80 kg; Informed consent to participate in the study. Exclusion criteria: having a history of pregabalin hypersensitivity

Intervention groups

Intervention group: One hour before thyroidectomy, they will receive single dose pregabalin 150 mg capsule orally. Control group: One hour before thyroidectomy, they will receive single dose of placebo capsules orally containing starch powder.

Main outcome variables

Post thyroidectomy pain severity in recovery room; the amount of opioid consumption post surgery; nausea; vomiting; dizziness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N36**

Registration date: **2024-02-12, 1402/11/23**

Registration timing: **prospective**

Last update: **2024-02-12, 1402/11/23**

Update count: **0**

Registration date

2024-02-12, 1402/11/23

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-08-20, 1403/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of pregabalin and placebo on post thyroidectomy pain of patients with thyroid carcinoma

Public title

Effect of pregabalin on postoperative thyroidectomy pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing thyroidectomy surgery Being at the age of 20-60 years Weight of 40 to 80 kg Having consent to participate in the study

Exclusion criteria:

History of any drug allergy

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

We made 30 cards and write letter A on 15 and B on the others. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and open it, based on selected letter (A or B) patients will be assigned to Pregabalin or Placebo group

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, pregabalin and placebo will be packed inside the capsule in the same shape and color with different codes. The person who prescribes the medicine and the person who evaluates the pain score and satisfaction of the patients will not know about the contents of the capsules (double-blind).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamadan University of Medical Sciences

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Shahid Fahmideh Avenue

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6517789971

Approval date

2024-01-20, 1402/10/30

Ethics committee reference number

IR.UMSHA.REC.1402.657

Health conditions studied**1****Description of health condition studied**

Thyroid carcinoma

ICD-10 code

D09.3

ICD-10 code description

Carcinoma in situ of thyroid and other endocrine glands

Primary outcomes**1****Description**

Postoperative pain Severity

Timepoint

6 hours after the operation

Method of measurement

with Visual Analogue Score

2**Description**

The amount of analgesic use

Timepoint

6 hours after the operation

Method of measurement

patient's medical record

3**Description**

Nausea

Timepoint

6 hours after the operation

Method of measurement

Ask the patient

4**Description**

Vomiting

Timepoint

6 hours after the operation

Method of measurement

Ask the patient

5

Description

Dizziness

Timepoint

6 hours after the operation

Method of measurement

Ask the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One hour before the operation, they will receive single dose of 150 mg oral pregabalin capsule.

Category

Treatment - Drugs

2

Description

Control group: One hour before the operation, they will receive single dose of oral capsules containing placebo.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Ruholah Abbasi

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Shahid Beheshti Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Reza Shokohi

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Ruholah Abbasi

Position

Department of ENT

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available