Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Abbas Moradi

Name of organization / entity
Hamedan University of Medical Of Science

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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 Univercity of Medical Sciences
Street address
Shahid Fahmideh Avenue
City
Hamadan
Province
Hamadan
Postal code
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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Sponsors / Funding sources

1

Sponsor
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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
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Position
Coach
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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