Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Concomitant Administration of Dexamethasone and Vitamin D before Total Thyroidectomy on Temporary Postoperative Hypocalcemia: A Clinical Trial Study

Protocol summary

Study aim

Investigating the effect of preoperative co-administration of dexamethasone and vitamin D on transient hypocalcemia after total thyroidectomy (Determination and comparison of the mean serum calcium levels before and after total thyroidectomy in the study groups based on age, gender, and the indication for thyroidectomy)

Design

This is a double-blind clinical trial with 4 arms conducted on 120 patients. For sequential random allocation, the sample size is divided by 4, and an equal number of codes labeled A, B, C, and D are placed in a bag. Each eligible patient will draw one code from the bag before surgery, which will determine their assigned treatment group.

Settings and conduct

This study is being conducted at Shahid Jalil Hospital in Yasuj. It is a double-blind study in which both participants and researchers are blinded. Participants provide are unaware of the content of the medication they receive. Similarly, the researchers do not know which group each participant has been assigned to.

Participants/Inclusion and exclusion criteria

Eligible participants are 18–70 years old, without history of diabetes, hypertension, pregnancy, drug addiction, relevant medication use, certain prior surgeries, and conditions affecting calcium, vitamin D, or parathyroid hormone levels.

Intervention groups

The "Dexamethasone and Vitamin D" intervention group receives a single intramuscular dose of vitamin D (200,000 IU) and a single intravenous dose of dexamethasone (8 mg) before the surgical incision. The "Vitamin D" group receives only a vitamin D before the incision, and the "Dexamethasone" group receives only dexamethasone. The control group does not receive any placebo medication. Patients who develop hypocalcemia (serum calcium level < 8 mg/dL) will be treated with oral calcium.

Main outcome variables

Serum calcium levels before and after surgery; average length of hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250627066277N1**
Registration date: **2025-07-18, 1404/04/27**
Registration timing: **prospective**

Last update: **2025-07-18, 1404/04/27**
Update count: **0**

Registration date

2025-07-18, 1404/04/27

Registrant information

Name

Saadat Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7001

Email address

dr.s.meh544@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-23, 1404/05/01

Expected recruitment end date

2026-05-21, 1405/02/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Concomitant Administration of Dexamethasone and Vitamin D before Total Thyroidectomy on Temporary Postoperative Hypocalcemia: A Clinical Trial Study

Public title
Effect of Concomitant Administration of Dexamethasone and Vitamin D before Total Thyroidectomy on Temporary Postoperative Hypocalcemia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 70 years Requiring total thyroidectomy Informed consent to participate in the study
Exclusion criteria:
Diabetes Hypertension Corticosteroid use for more than 7 days within the past three months Pregnancy Use of medications affecting calcium metabolism History of ischemic heart disease Drug addiction Preoperative hypocalcemia Presence of parathyroid adenoma Presence of any underlying condition that affects levels of parathyroid hormone, vitamin D, calcium, or albumin (e.g., chronic kidney disease) History of major prior procedures such as total laryngectomy or parathyroidectomy
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
For sequential random allocation of participants to the study groups, the sample size is divided by 4, and an equal number of codes labeled A, B, C, and D are placed in a bag. Each eligible participant will draw one code from the bag before surgery, and their treatment group will be determined based on the selected code.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both participants and researchers are double-blinded in this study. Participants provide informed consent to take part in the study but are unaware of the content of the medication they receive. Similarly, the researchers do not know which group each participant has been assigned to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences
Street address
Shahid Gharani Blvd.
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591387493
Approval date
2025-06-19, 1404/03/29
Ethics committee reference number
IR.YUMS.REC.1404.068

Health conditions studied

1

Description of health condition studied
Post-Thyroidectomy Hypocalcemia
ICD-10 code
E83.5
ICD-10 code description
Disorders of calcium metabolism

Primary outcomes

1

Description
Serum calcium levels before and after surgery
Timepoint
Every 12 hours for two days
Method of measurement
Serum calcium levels test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: a single intramuscular dose of vitamin D (200,000 IU) and a single intravenous dose of dexamethasone (8 mg), Intervention group 2: a single intramuscular dose of vitamin D (200,000 IU) , Intervention group 3: a single intravenous dose of dexamethasone (8 mg)
Category
Treatment - Drugs

2

Description
Control group: No drugs given
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Jalil Hospital at Yasuj city
Full name of responsible person
Saadat Mehrabi
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Web page address
https://shahidjalil.yums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Cirruse Salehnasab
Street address
Deputy of Research and Technology, Yasuj University of Medical Sciences, Shahid Motahhari Blvd.
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Postal code
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Phone
+98 74 3334 6078
Email
research@yums.ac.ir
Web page address
https://research.yums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Saadat Mehrabi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
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Person responsible for updating data

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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Patient data, including demographic information and laboratory results, may be published without revealing the patients' identities.
When the data will become available and for how long
The access period will begin after the publication of the results.
To whom data/document is available
The study data will be available only to researchers affiliated with academic and scientific institutions.
Under which criteria data/document could be used
The data from this study will only be available for use in meta-analyses and systematic reviews.
From where data/document is obtainable
To request access to the study data, please contact Dr. Saadat Mehrabi, the principal investigator, via email at dr.s.meh544@gmail.com.
What processes are involved for a request to access data/document
The data will be provided to the researcher as soon as possible after the email is received and the request is submitted.
Comments