

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

Kohgiluyeh-va-Boyerahmad

**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

##### Street address

Shahid Jalil Hospital, Shahid Gharani Blvd.

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

۷۵۹۱۳۸۷۴۹۳

##### Phone

+98 74 3333 7001

##### Fax

+98 74 3333 7001

##### Email

shahidjalil@yums.ac.ir

##### 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

Cirrus Salehnasab

##### Street address

Deputy of Research and Technology, Yasuj University of Medical Sciences, Shahid Motahhari Blvd.

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591741417

##### 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

##### Street address

Shahid Jalil Hospital, Shahid Gharani Blvd.

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##### Province

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dr.s.meh544@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

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dr.s.meh544@gmail.com

**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****Person responsible for updating data****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Saadat Mehrabi

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