

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of identifying parathyroid glands using methylene blue on reducing hypocalcemia after thyroidectomy

#### Protocol summary

##### Study aim

Determining the relationship between the use of methylene blue and the reduction of hypocalcemia after thyroidectomy.

##### Design

Clinical trial with control group, without randomization, on 54 patients

##### Settings and conduct

This study will be conducted on patients who are candidates for thyroidectomy surgery in the operating room of Madani Hospital in Karaj. Patients will be divided into intervention and control groups based on inclusion criteria without randomization and based on the surgeon's opinion.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Thyroidectomy for any reason 2. Age over 18 years Exclusion criteria: 1. History of calcium disorders 2. Abnormal calcium before surgery 3. Metastatic cancers 4. Previous history of thyroid surgery

##### Intervention groups

Methylene blue 1% (1 mL [10 mg]) will be sprayed over the thyroid lobe and perilobar area, which include the parathyroid glands, the inferior thyroid artery, and the recurrent laryngeal nerve. After 5 minutes and the parathyroid glands have stained, meticulous dissection and ligation of the terminal branches of the inferior thyroid artery and vein will be done to preserve the vessels supplying the parathyroid glands. Subsequently, the gland will be separated from the trachea, followed by an adequate inspection to ensure that no parathyroid glands were inadvertently removed. The control group also underwent traditional surgery and the parathyroid glands are preserved whenever possible.

##### Main outcome variables

calcium level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250331065186N1**  
Registration date: **2025-06-28, 1404/04/07**  
Registration timing: **registered\_while\_recruiting**

Last update: **2025-06-28, 1404/04/07**

Update count: **0**

##### Registration date

2025-06-28, 1404/04/07

##### Registrant information

###### Name

Abbas Alizade

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3350 7042

###### Email address

abbas.alz7676@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-04-30, 1404/02/10

##### Expected recruitment end date

2025-08-23, 1404/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of identifying parathyroid glands using methylene blue on reducing hypocalcemia after thyroidectomy

## Public title

Methylene blue as identifier of Parathyroid Glands

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

1. Thyroidectomy surgery for any reason 2. Over 18 years of age

### Exclusion criteria:

1. History of calcium disorders 2. Abnormal calcium before surgery 3. Metastatic cancers 4. Previous history of thyroid surgery

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **54**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

##### Street address

No. 8, Saffarzadeh Alley, Golshahr Street

##### City

karaj

##### Province

Alborz

##### Postal code

۳۱۹۸۷۶۴۶۵۳

#### Approval date

2025-02-22, 1403/12/04

#### Ethics committee reference number

IR.ABZUMS.REC.1403.335

## Health conditions studied

### 1

#### Description of health condition studied

Thyroid disease

#### ICD-10 code

E07.9

#### ICD-10 code description

Disorder of thyroid, unspecified

## Primary outcomes

### 1

#### Description

calcium level

#### Timepoint

One day before and one day after the operation

#### Method of measurement

automated techniques using COBAS integra reagents (Cobas Integra, Roche Diagnostics, Switzerland)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention Group: In this group, patients will undergo a total thyroidectomy procedure following standard surgical protocols, with the addition of methylene blue as an adjunct to facilitate the identification and preservation of the parathyroid glands. The agent used is methylene blue 1%, with a concentration of 10 mg/mL. A total volume of 1 mL (equivalent to 10 mg) will be sprayed once during the surgery using a sterile syringe equipped with a spray nozzle or atomizer. The spray will be applied evenly over the surface of the thyroid lobe and the surrounding area, which includes the likely locations of the parathyroid glands, the recurrent laryngeal nerve, and branches of the inferior thyroid artery. Methylene blue enhances visual differentiation, as the parathyroid glands absorb less dye compared to surrounding tissues, thus helping the surgeon identify and preserve them more effectively. The application of the dye is done only once during the procedure, after full exposure of the thyroid lobe. All other aspects of the surgery are similar to the control group and include the classic open cervical approach, the use of scalpel, electrocautery, suction, and performance of the procedure under general anesthesia. No educational sessions or training interventions will be provided to the surgeons or operating room staff during the study.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: In this group, patients will undergo a total thyroidectomy procedure performed according to the

standard protocols, without the use of any adjunctive agents for the identification of the parathyroid glands. Preservation of the parathyroid glands will rely solely on the direct visualization and the experience and skill of the surgeon in distinguishing parathyroid tissue. The surgery will be performed using the classic open cervical approach under general anesthesia. Standard surgical instruments such as scalpel, electrocautery device (Valleylab Force FX, manufactured by Medtronic), and suction will be used throughout the procedure. The general steps of the operation are as follows: a transverse incision will be made along the midline of the neck (Kocher incision); the pretracheal muscles will be retracted; the recurrent laryngeal nerve will be identified and carefully preserved; the thyroid tissue will be identified and completely removed; and maximum effort will be made to preserve the parathyroid glands through direct observation without the use of any dyes or chemical agents. No substances will be used for staining or marking the parathyroid glands. Furthermore, no educational intervention or additional training will be provided to the surgeons or the operating room staff during the study.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Madani hospital

##### Full name of responsible person

Mojtaba Ahmadi Nejad

##### Street address

Jahanshahr, Madani Hospital

##### City

Karaj

##### Province

Alborz

##### Postal code

3143744693

##### Phone

+98 26 3330 0000

##### Email

Mojtaba.ahmadinejad@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Alborz University of Medical Sciences

##### Full name of responsible person

Razieh Lotfi

##### Street address

Research and Technology Deputy, Safarian Alley, 45-Meter Golshahr, Karaj, Iran

##### City

karaj

#### Province

Alborz

#### Postal code

3198764653

#### Phone

+98 26 3464 3705

#### Email

Research@abzums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Alborz 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

Karaj University of Medical Sciences

##### Full name of responsible person

Abbas Alizade

##### Position

Medical student

##### Latest degree

A Level or less

##### Other areas of specialty/work

General Surgery

##### Street address

Madani hospital, Madani square, Jahanshahr, karaj

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Karaj

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+98 26 3350 7042

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Karaj University of Medical Sciences

##### Full name of responsible person

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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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

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

Karaj University of Medical Sciences

**Full name of responsible person**

Abbas Alizade

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Surgery

**Street address**

Madani Hospital, Madani Square, Jahanshahr, Karaj