

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 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 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

۳۱۹۸۷۶۴۵۳

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

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Karaj

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Alborz

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3143744693

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+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

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karaj

Province

Alborz

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3198764653

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+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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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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

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Fax**Email**

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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