Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 perilober 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

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Iran (Islamic Republic of)

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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
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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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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
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Person responsible for updating data

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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