Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

A comparative study on the efficacy of injecting versus oral vitamin D supplementation prior to thyroidectomy on reducing inflammation post-operation: A randomized parallel clinical trial

Protocol summary

Study aim

The aim of this study was to investigate and compare the effectiveness of injection versus oral vitamin D supplementation before thyroidectomy on postoperative inflammation and hypocalcemia.

Design

A randomized parallel group single blind clinical trial, phase 2, on 200 patients.

Settings and conduct

This study will be conducted in adult patients scheduled to undergo thyroidectomy. Those involved in data collection and analysis will be blinded to the patient allocation. Codes to identify the groups will be assigned and maintained by a third party not involved in data collection and analysis. These codes will not be disclosed to the investigators until the study is complete. The investigators and those responsible for data analysis will be blinded to the group allocation. The allocation to groups will be coded and the key to them will be revealed after the study is completed and the final analysis is complete.

Participants/Inclusion and exclusion criteria

Patients aged 18 years or older scheduled to undergo thyroidectomy will be enrolled in the study. Patients whose serum levels of vitamin D are below 30 ng/ml will be included in the study. Patients who used any form of vitamin D or calcium supplementation prior to the study, those with renal insufficiencies (eGFR ˂ 60mL/min/1.73m 2), active liver diseases, any conditions that affect serum vitamin D levels or absorption of Vitamin D and calcium (such as celiac disease or small intestinal disorder), drugs (including steroids, antiepileptic drugs, bisphosphonates, cisplatin, aminoglycosides, diuretics, or proton pump inhibitors), cardiac diseases and coagulopathies will be excluded.

Intervention groups

One group will receive vitamin D3 (cholecalciferol) 50,000 IU orally every day for 6 days before surgery, and the other group will receive a single dose of vitamin D3 (Cholecalciferol) 300,000 IU, IM injection one day before surgery.

Main outcome variables

The primary outcome will be the changes in inflammatory marker including CRP and calcium levels, after thyroidectomy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221016056199N2**
Registration date: **2026-08-25, 1405/06/03**
Registration timing: **prospective**

Last update: **2026-08-25, 1405/06/03**
Update count: **0**

Registration date

2026-08-25, 1405/06/03

Registrant information

Name
Kimia Falamarzi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3646 3245
Email address
kimiafalamarzi@yahoo.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-09-15, 1405/06/24

Expected recruitment end date

2026-12-15, 1405/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the efficacy of injecting versus oral vitamin D supplementation prior to thyroidectomy on reducing inflammation post-operation: A randomized parallel clinical trial

Public title

Effects of vitamin D supplementation in thyroidectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18 years and older Patients who are scheduled to undergo thyroidectomy Patients with serum levels of vitamin D below 30 ng/mL

Exclusion criteria:

Patients who used any form of vitamin D or calcium supplementation prior to the study Patients with renal insufficiencies (eGFR ˂ 60mL/min/1.73m 2) Patients with active liver diseases Patients with any conditions that affect serum vitamin D levels or absorption of Vitamin D and calcium (such as Celiac disease or any small intestinal disorder) Patients on drugs (including steroids, antiepileptic drugs, bisphosphonates, cisplatin, aminoglycosides, diuretics, or proton pump inhibitors) Patients with cardiac diseases Patients with coagulopathies

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to each intervention group based on a random list generated by computer. Eligible patients will be randomly assigned in a 1:1 ratio to each group using computer-generated permuted block randomozation sequence with variable block sizes of 4 and 6. The randomization sequence will be generated and maintained by an independent person who is not involved in data collection and analysis and will be revealed only after completion of the study and final analysis.

Blinding (investigator's opinion)

Single blinded

Blinding description

Those who collect and analyze data will be blinded to patients' allocation. A certain code that identifies each group will be used and will be kept by a third person who has no role in the data collection and analysis and will not be revealed to the researchers until the end of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz university of medical sciences, school of medicine, Emam Hossein Square, Zand Blvd

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2026-01-06, 1404/10/16

Ethics committee reference number

IR.SUMS.REC.1404.549

Health conditions studied

1

Description of health condition studied

Thyroid disease

ICD-10 code

E34

ICD-10 code description

Other endocrine disorders

Primary outcomes

1

Description

Inflammatory marker C-reactive protein (CRP)

Timepoint

before intervention and 24 hours after thyroidectomy

Method of measurement

lab kit to measure CRP

Secondary outcomes

1

Description
Calcium serum level
Timepoint
before intervention and 24 hours after thyroidectomy
Method of measurement
lab kit for measuring serum calcium levels

Intervention groups

1

Description
Intervention group: The patients in this group will receive vitamin D3 (cholecalciferol) 50,000 IU orally every day for 6 days before thyroidectomy
Category
Prevention

2

Description
Intervention group: The patients in this group will receive a single dose of vitamin D3 (Cholecalciferol) 300000 IU, IM injection one day before surgery.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Maryam Hosseini
Street address
Zand st, Shiraz
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3230 5410
Email
Info@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr, Hamid Mohammadi
Street address
Zand St
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 3230 5410
Email
info@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Hosseini
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
Trauma Research Center, Rajaee Hospital, Shahid Chamran Blvd
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 3625 4206
Email
hssn.mary28@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Maryam Hosseini

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Trauma Research Center, Rajaee Hospital, Shahid Chamran Blvd

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Phone
+98 71 3625 4206

Email
hssn.mary28@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Maryam Hosseini

Position
Assistant Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable