Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A comparative study of hypocalcemia and complications caused by recurrent laryngeal nerve injury during total thyroidectomy in complete exposure versus non exposure of the recurrent laryngeal nerve

Protocol summary

Study aim

Determining and comparing the percentage of patients who need tracheostomy; Incidence of dysphagia, hoarseness, aphonia, average score of hypocalcemia, hematoma after total thyroidectomy surgery with and without exploration of the recurrent laryngeal nerve in each of the study groups.

Design

Clinical trial with control group, with parallel group, without blinding, randomized, without phase, on 114 patients. The rand function of Excel software is used for randomization.

Settings and conduct

Total thyroidectomy candidate patients referred to Shahid Jalil Hospital in Yasouj city will be included in the study if they meet the inclusion criteria. The study will be a post-test with a control group. Recurrent nerve exploration will be done for the intervention group. Compared to the previous group, the surgery of the control group will be performed without exploration by the surgeon.

Participants/Inclusion and exclusion criteria

Declaring willingness to participate in the study after filling out the informed consent form by the patient, the patient is a candidate for total thyroidectomy, age between 18-70, no previous neck surgery, no history of neck radiation, no vocal cord disorders, no History of parathyroid hormone disorder, no kidney disorders, preoperative blood calcium level within normal range, patient's unwillingness to continue cooperation, patient's death.

Intervention groups

Candidate patients for total thyroidectomy, provided they meet the entry criteria

Main outcome variables

The percentage of patients requiring tracheostomy Incidence of dysphagia, voice harshness, aphonia, hypocalcemia average score, hematoma after total thyroidectomy surgery with and without recurrent laryngeal nerve exploration is different in each of the study groups;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240601061973N1**
Registration date: **2024-10-09, 1403/07/18**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-09, 1403/07/18**
Update count: **0**

Registration date

2024-10-09, 1403/07/18

Registrant information

Name

Saadat Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7001

Email address

dr.shimafard@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-22, 1403/06/01

Expected recruitment end date

2025-01-20, 1403/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of hypocalcemia and complications caused by recurrent laryngeal nerve injury during total thyroidectomy in complete exposure versus non exposure of the recurrent laryngeal nerve

Public title

A comparative study of hypocalcemia and complications caused by recurrent laryngeal nerve injury during total thyroidectomy in complete exposure versus non exposure of the recurrent laryngeal nerve

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No history of radiation to the neck، Absence of any disorder in the vocal cords، Having no history of parathyroid hormone disorders ، Having no history of renal disease , Preoperative blood calcium level within normal range , Declaring willingness to participate in the study after filling the informed consent form by the patient , The patient is a candidate for total thyroidectomy , Age between 18-70 , No history of previous neck surgery

Exclusion criteria:

The patient's unwillingness to continue cooperation
Death of the patient

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: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization is simple randomization. If the patients meet the inclusion criteria, they will be placed in the intervention and control groups one at a time, and this will continue until the desired sample size is reached.

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 Yasouj University of Medical Sciences

Street address

Jalil Hospital; Emam reza St ; shahid Gharani Blvd; Yasouj Town

City

Yasouj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591387493

Approval date

2024-05-25, 1403/03/05

Ethics committee reference number

IR.YUMS.REC.1403.016

Health conditions studied

1

Description of health condition studied

Postprocedural hypoparathyroidism

ICD-10 code

E89.2

ICD-10 code description

Postprocedural hypoparathyroidism

Primary outcomes

1

Description

hypocalcemia

Timepoint

Before the operation, 7 and 14 days after the operation

Method of measurement

Blood calcium with a laboratory kit,

Secondary outcomes

1

Description

Need for tracheostomy, aphonia, voice harshness, dysphagia, hematoma

Timepoint

Immediately after the operation, 7 and 14 days later

Method of measurement

Based on the history of the patient and looking and examination by the surgeon

Intervention groups

1

Description
Intervention group: exploring the recurrent nerve during thyroidectomy
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Jalil Hospital of Yasouj town
Full name of responsible person
Saadat Mehrabi
Street address
Shahid Jalil Hospital; Emamreza St ; Shahid Gharani Blvd; Yasouj Town
City
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Kohgilouyeh-va-Boyrahmad
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7591387493
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dr.shimafard@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Saadat Mehrabi
Street address
Jalil Hospital; Emamreza St; Shahid Gharani Blvd
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dr.s.meh544@gmail.com
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
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Person responsible for updating data

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Shima Farde Manouchehri

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

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dr.shimafard@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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Laboratory results and recorded evidence can be published if the patient's name is removed

When the data will become available and for how long
April 2024 to April 2025

To whom data/document is available
Doctors and medical students

Under which criteria data/document could be used
There is no limit

From where data/document is obtainable
Jalil hospital in Yasouj Town

What processes are involved for a request to access data/document
Send request to email dr.shimafard@gmail.com

Comments