

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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-Boyerahmad

**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

Yasouj

#### Province

Kohgilouyeh-va-Boyr Ahmad

#### Postal code

7591387493

#### Phone

+98 74 3333 7002

#### Email

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

#### City

Yasouj

#### Province

Kohgilouyeh-va-Boyr Ahmad

#### Postal code

7591387493

#### Phone

+98 74 3333 7001

#### Email

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

#### Street address

Jalil Hospital; Emamreza St; Shahid Gharani Blvd

#### City

Yasouj

#### Province

Kohgilouyeh-va-Boyr Ahmad

#### Postal code

7591387493

#### Phone

0098 74 3333002

#### Email

dr.s.meh544@gmail.com

## Person responsible for scientific 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

#### Street address

Jalil hosp; Emamreza St; Shahid Gharani Blvd

#### City

Yasouj

#### Province

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#### Postal code

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#### Phone

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#### Email

## 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

**Street address**

Jalil hospital;EmamrezaSt; Shahid Gharani Blvd

**City**

Yasouj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

7591387493

**Phone**

+98 74 3333 7003

**Email**

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**