

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative evaluation of surgical result of sonographic assisted minimally invasive parathyroidectomy And conventional parathyroidectomy in primary hyperparathyroidism patients

#### Protocol summary

##### Study aim

Determining the size and approximate location of the parathyroid to reduce surgery time and complications of minimally invasive parathyroidectomy with the help of ultrasound (MIP sono assisted) compared to conventional parathyroidectomy.

##### Design

Patients with primary hyperparathyroidism due to parathyroid adenoma who underwent minimally invasive parathyroidectomy will form the study population. The group that underwent surgery with the conventional method forms the control group.

##### Settings and conduct

The study of a randomized clinical trial on patients with primary hyperparathyroidism due to parathyroid adenoma who underwent minimally invasive parathyroidectomy surgery at Shariati Hospital will form the study group, and the group that underwent conventional surgery form the control group.

##### Participants/Inclusion and exclusion criteria

Inclusion: Patients with primary hyperthyroidism  
exclusion : Patients whose parathyroid tumor is more than 4 cm The presence of any chronic disease or malignancy in the thyroid or parathyroid region or suffering from any systemic and malignant disease  
Patients with secondary or tertiary hyperthyroidism

##### Intervention groups

In the intervention group, parathyroidectomy was performed minimally invasively with the help of ultrasound. In the control group, parathyroidectomy was performed conventionally.

##### Main outcome variables

PTH drop more than 50% before and after excision

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220822055773N1**

Registration date: **2022-08-31, 1401/06/09**

Registration timing: **retrospective**

Last update: **2022-08-31, 1401/06/09**

Update count: **0**

##### Registration date

2022-08-31, 1401/06/09

##### Registrant information

##### Name

shirzad nasiri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8490 2450

##### Email address

dr.sh.nasiri@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2016-10-22, 1395/08/01

##### Actual recruitment start date

2016-09-10, 1395/06/20

##### Actual recruitment end date

2016-12-10, 1395/09/20

##### Trial completion date

2017-03-18, 1395/12/28

##### Scientific title

Comparative evaluation of surgical result of sonographic

assisted minimally invasive parathyroidectomy And conventional parathyroidectomy in primary hyperparathyroidism patients

#### Public title

Comparative evaluation of surgical result of sonographic assisted minimally invasive parathyroidectomy And conventional parathyroidectomy in primary hyperparathyroidism patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with primary hyperthyroidism

##### Exclusion criteria:

Patients whose parathyroid tumor is more than 4 cm The presence of any chronic disease or malignancy in the thyroid or parathyroid region or suffering from any systemic and malignant disease Patients with secondary or tertiary hyperthyroidism

#### Age

No age limit

#### Gender

Both

#### Phase

3

#### Groups that have been masked

No information

#### Sample size

Target sample size: **96**

Actual sample size reached: **96**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization method: It is simple, a number was assigned to each patient, then they were placed in the online platform [www.randomization.com](http://www.randomization.com) to randomize the number, and two groups A and B were randomized as intervention and control groups. Randomization Unit: Individual Output of the random instrument: patients with primary hyperthyroidism who have been definitively diagnosed clinically and laboratory, both male and female, without age limit.

#### 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

Tehran university of medical sciences ethics committee

#### Street address

Tehran University of Medical Sciences, Poursina Avenue, Qods Street, Enqelab Square, Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1417613151

#### Approval date

2016-08-22, 1395/06/01

#### Ethics committee reference number

IR.TUMS.REC.1395.2661

### Health conditions studied

#### 1

##### Description of health condition studied

surgical result of sonographic assisted minimally invasive parathyroidectomy And conventional parathyroidectomy in primary hyperparathyroidism patients

#### ICD-10 code

E21.0

#### ICD-10 code description

Primary hyperparathyroidism

### Primary outcomes

#### 1

##### Description

Success of MIP surgery in patients with primary hyperparathyroidism based on changes in serum PTH levels

##### Timepoint

PTH measurement before surgical incision, PTH measurement before excision, PTH measurement 5 minutes after excision and finally PTH measurement 10 minutes after excision

##### Method of measurement

Sonographic investigation to localize overactive parathyroid and serum level of PTH during surgery and parathyroid scan

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: In this study, the patients entered the study after being selected based on the entry and exit criteria, then pre-operative tests and examinations for MIP (minimally invasive parathyroidectomy) candidates, including ultrasound examination to localize the overactive parathyroid and serum measurement of

the PTH hormone level. During the operation and scanning of the parathyroid will be performed and finally the surgery will be performed in a minimally invasive way to remove the overactive parathyroid. Then necessary tests such as PTH measurement before surgical incision, PTH measurement before excision, PTH measurement 5 minutes after excision and finally PTH measurement 10 minutes after excision will be measured.

#### Category

Treatment - Surgery

## 2

#### Description

Control group: In this study, the patients entered the study after being selected based on the entry and exit criteria, then pre-operative tests and examinations for conventional parathyroidectomy candidates, including the serum measurement of the PTH hormone level during the operation and the parathyroid scan, will be performed. Finally, conventional surgery will be performed to remove the overactive parathyroid. Then necessary tests such as PTH measurement before surgical incision, PTH measurement before excision, PTH measurement 5 minutes after excision and finally PTH measurement 10 minutes after excision will be measured. In patients who are candidates for parathyroidectomy by conventional method, parathyroid scan and ultrasound will be used to localize the overactive parathyroid before the operation.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shariati hospital

##### Full name of responsible person

Shirzad Nasiri Zaviki

##### Street address

Jalal Al Ahmad Three Roads, North Kargar St.,

##### City

Tehran

##### Province

Tehran

##### Postal code

1411713135

##### Phone

+98 21 8863 3039

##### Email

shariatihosp@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Shahin Akhoondzadeh

#### Street address

Poursina street, Qods street, Enqelab square, Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1417613151

#### Phone

+98 21 6111 3411

#### Email

razi@tums.ac.ir

#### Grant name

Research deputy, School of Medicine, Tehran University of Medical Sciences

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

Shirzad Nasiri Zaviki

##### Position

Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

General Surgery

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Dr.sh.nasiri@gmail.com

## Person responsible for scientific inquiries

### Contact

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Tehran University of Medical Sciences

**Full name of responsible person**

Shirzad Nasiri Zaviki

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## Person responsible for updating data

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Tehran University of Medical Sciences

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## 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Data will be shared after blinding of datasheet.

**When the data will become available and for how long**

Data will be shared within 6 months after publication.

**To whom data/document is available**

Data will be accessible for researchers affiliated to universities

**Under which criteria data/document could be used**

Data can be used for further meta-analysis after permission of the person responsible for this project

**From where data/document is obtainable**

Data request should be sent through email for the person responsible for this project. Dr. Shirzad Nasiri Zivaki  
Dr.sh.nasiri@gmail.com

**What processes are involved for a request to access data/document**

Following the primary request, all the researchers will be informed by the responsible person and after permission the data will be shared.

**Comments**