

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 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.,

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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

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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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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