Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Public title
Comparative evaluation of surgical result of sonographic assisted minimally invasive parathyroidectomy And conventional parathyroidectomy in primary hyparathyroidisem 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 hyparathyroidisem 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

Researach 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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Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

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Person responsible for updating data

Contact

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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