Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Comparative effectiveness of treating primary hyper-parathyroid patients due to parathyroid adenoma with parathyroidectomy versus ultrasonography-guided alcohol ablation

Protocol summary

Study aim
Comparison of treating primary hyperparathyroidism due to parathyroid adenoma with alcohol ablation under ultrasound guide compared with surgical resection of adenoma.

Design
Randomized none-blinded parallel clinical trial

Settings and conduct
Patients who refer to medical centers with suspected signs and symptoms of hypercalcemia and hyperparathyroidism, after evaluating their inclusion and non-inclusion criteria and obtaining informed consent and knowledge of both treatments and equal probability of being in each group. Due to ethical issues, no blinding will occur. Still, the order of placement in each analysis group will be determined, and the details of this will be hidden from researchers until the end of the project. An interventional radiologist ablates one group of patients' adenoma under the guidance of ultrasound with alcohol. After the operation, the serum levels of calcium and parathyroid hormone are regularly evaluated, and an experienced surgeon resects the other group. It is evaluated in the same way after the operation.

Participants/Inclusion and exclusion criteria
Patients with symptomatic benign parathyroid adenoma confirmed by ultrasound, systemic scan, and fine-needle aspiration who wish to participate in the study and who do not suspect MEN2 or MEN1 syndrome, malignancy, secondary or tertiary hyperparathyroidism will be selected for the study.

Intervention groups
Patients who meet the admission criteria and do not meet the exclusion criteria will be randomly divided into two groups: alcohol injection into the adenoma under the guidance of an ultrasond by an experienced radiologist or adenoma resection surgery by an experienced surgeon.

Main outcome variables
Comparison between groups and intragroup mean and changes in corrected serum calcium and parathyroid hormone levels after each treatment intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210204050241N1**
Registration date: **2021-04-26, 1400/02/06**
Registration timing: **prospective**

Last update: **2021-04-26, 1400/02/06**
Update count: **0**

Registration date
2021-04-26, 1400/02/06

Registrant information

Name
Alireza Firoozfar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3236 5742

Email address
alireza.firoozfar@resident.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-05, 1400/02/15

Expected recruitment end date
2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effectiveness of treating primary hyper-parathyroid patients due to parathyroid adenoma with parathyroidectomy versus ultrasonography-guided alcohol ablation

Public title

Comparison of the results of treatment of the primary parathyroid adenoma with surgery or ablation with ethanol.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with symptomatic benign parathyroid adenoma confirmed by ultrasound, MIBI scan, and fine needle aspiration

Exclusion criteria:

Patients with MEN1 or MEN2 syndrome Patients with suspected parathyroid malignant adenoma Patients with secondary or tertiary hyperparathyroidism Not willing to participate in the trial GFR<30 ml/min/1.72 m2 age above 50

Age

To **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are allocated into either the intervention or control group using a non-stratified block randomization method to keep an even randomization ratio of (1:1). Random Allocation Software is used by our expert analytics to determine the list and group of patients. He is blinded to the selection process and pre-and post-operative assessments. The block size will be equal and is set to 4, the sufficient and estimated sample size will be 120, then the allocation code is set to sequential. The analytics will use the output of software to determine the sequence and allocation of patients. Then each code is written on a non-transparent envelope and a paper is put in it in which the "Surgery" or "Alcohol" is written on the paper. The series of the envelope will be according to the software's list and they will keep in a large box with a locker. The analytics has the key for the box and this box will be kept in his room which the analytics has its only key and has no windows. As the patients enrolled in the study sequentially, the analytics use the designated envelope. The mechanism of randomization and block size will not be revealed to the principal investigator and other involved physicians until the end of the trial.

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 isfahan university of medical sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib blvd. Azadi Sq.

City

isfehan

Province

Isfehan

Postal code

81746-73461

Approval date

2021-03-27, 1400/01/07

Ethics committee reference number

IR.MUI.MED.REC.1400.003

Health conditions studied

1

Description of health condition studied

Benign parathyroid adenoma

ICD-10 code

D35.1

ICD-10 code description

Benign neoplasm of parathyroid gland

Primary outcomes

1

Description

Serum calcium level

Timepoint

Before the intervention, 24 hours, two weeks, three months, and six months after the intervention

Method of measurement

Blood sample tests

2

Description
Serum PTH level
Timepoint
Before the intervention, 24 hours, two weeks, three months, and six months after the intervention
Method of measurement
Blood sample tests

Secondary outcomes

1

Description
Adenoma recurrence (reoperation or re-injection of alcohol)
Timepoint
Within 3 months and 6 months after the intervention
Method of measurement
Changes in serum calcium and parathyroid hormone levels after intervention

Intervention groups

1

Description
Intervention group 1: Classic surgical resection of parathyroid adenoma with a neck incision
Category
Treatment - Surgery

2

Description
Intervention group 2: After complete neck ultrasonography with doppler, the number, size, location, and vascularity index of adenoma will be evaluated. After preparation and draping, under local anesthesia, hydrodissection of the surrounding tissue by injecting distilled water will be performed under ultrasonography guide and the adenoma will be released from the trachea, esophagus, and recurrent laryngeal nerve. The adenoma then will be ablated with pure sterile ethanol (99.5%) until becomes avascular. 1-4 cc of ethanol will be injected each time according to the size and vascularity index of the adenoma.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Alireza Firozfar
Street address
Alzahra hospital, sofe bolvar, Isfahan
City
Isfehan
Province
Isfehan
Postal code
81746 75731
Phone
+98 31 3620 2020
Email
alireza.firoozfar@resident.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Deputy of Research of Isfahan University of Medical Sciences, Hezar Jerib blvd. Azadi sq. Isfahan
City
isfehan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Alireza Firoozfar
Position
Resident of general surgery
Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Surgery office, Alzahra hospital, Sofeh Blvd.

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3236 5742

Fax

Email

alireza.firoozfar@resident.mui.ac.ir

Person responsible for scientific inquiries

Contact

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Esfahan University of Medical Sciences

Full name of responsible person

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Alireza Firoozfar

Position

Resident

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available