

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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 ultrasound 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 hyperparathyroid 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 m<sup>2</sup> 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**

isfahan

**Province**

Isfahan

**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 Firoozfar

#### **Street address**

Alzahra hospital, sofe bolvar, Isfahan

### **City**

Isfahan

### **Province**

Isfahan

### **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**

isfahan

#### **Province**

Isfahan

#### **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**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3236 5742

**Fax**

**Email**

alireza.firoozfar@resident.mui.ac.ir

**Person responsible for scientific 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**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3236 5742

**Fax**

**Email**

alireza.firoozfar@resident.mui.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Alireza Firoozfar

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

**Street address**

Surgery office, Alzahra hospital, Sofeh Blvd.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3236 5742

**Fax**

**Email**

alireza.firoozfar@resident.mui.ac.ir

**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