

# 4D CT-guided focused parathyroidectomy: a paradigm shift from experience-based surgery in end-stage renal disease patients with medically refractory secondary hyperparathyroidism

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<b>Registration date</b> 14/07/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
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		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The main aim of this study is to investigate whether a 4D CT scan can be used for gland localization before surgery for end-stage renal disease (ESRD) patients with secondary or tertiary hyperparathyroidism, replacing traditional surgeon experience-based surgery. Hyperparathyroidism is an increase in parathyroid hormone levels in the blood.

### Who can participate?

ESRD patients with secondary or tertiary hyperparathyroidism who have not previously undergone any parathyroid surgery

### What does the study involve?

Patients who received 4D CT-guided focused parathyroidectomy and those who underwent experience-based surgery. The study will compare surgical outcomes, biochemical control, and perioperative complications between the two groups at 1 week, 1 month, 3 months, 6 months, and 12 months postoperatively.

### What are the possible benefits and risks of participating?

The potential benefits include reduced surgical time and unnecessary anesthetic risks. Patients may be exposed to higher doses of radiation as part of the imaging protocol.

### Where is the study run from?

Linkou Chang Gung Memorial Hospital (Taiwan)

### When is the study starting and how long is it expected to run for?

October 2024 to June 2025

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Dr Yungyuan Chan, isc@cgmh.org.tw

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Yungyuan Chan

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

202201157B0

## Study information

### Scientific Title

4D CT-guided focused parathyroidectomy versus experience-based surgery in end-stage renal disease patients with medically refractory secondary hyperparathyroidism: impact on surgical outcomes and biochemical control

### Study objectives

To evaluate the effectiveness of 4D CT-guided focused parathyroidectomy compared to experience-based surgery in end-stage renal disease (ESRD) patients with medically refractory secondary hyperparathyroidism in terms of biochemical control and surgical success rate.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 10/10/2024, Institutional Review Board of Linkou Chang Gung Memorial Hospital (No. 5, Fuxing St., Guishan Dist., Taoyuan City, 333, Taiwan; +886 (0)33281200; isc@cgmh.org.tw), ref: 202201157B0

## **Study design**

Retrospective comparative cohort study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic, Treatment, Safety

## **Health condition(s) or problem(s) studied**

End-stage renal disease (ESRD) patients with medically refractory secondary hyperparathyroidism

## **Interventions**

This is a retrospective comparative cohort study analyzing end-stage renal disease (ESRD) patients with medically refractory secondary hyperparathyroidism who underwent parathyroidectomy. Patients will be divided into two groups based on the surgical approach: those who received 4D CT-guided focused parathyroidectomy and those who underwent experience-based surgery. The study will compare surgical outcomes, biochemical control, and perioperative complications between the two groups.

### **Study Arm 1: 4D CT-Guided Focused Parathyroidectomy Group**

Intervention: Preoperative 4D CT imaging for parathyroid localization followed by focused parathyroidectomy

Procedure: Patients undergo a 4D CT scan within 2-4 weeks before surgery. Based on imaging results, a targeted surgical approach is performed focusing on the identified abnormal parathyroid glands

Duration: Single surgical procedure with immediate postoperative monitoring

Follow-up: 1 week, 1 month, 3 months, 6 months, and 12 months postoperatively

### **Study Arm 2: Experience-Based Surgery Group**

Intervention: Conventional parathyroidectomy based on the surgeon's clinical experience and intraoperative findings

Procedure: Traditional surgical exploration without preoperative localization imaging, relying on the surgeon's experience for gland identification and removal

Duration: Single surgical procedure with immediate postoperative monitoring

Follow-up: 1 week, 1 month, 3 months, 6 months, and 12 months postoperatively

### **Randomization Process:**

This is a retrospective comparative study; therefore, no randomization was performed. Patient allocation to study arms was based on the surgical approach used during their treatment period (before and after implementation of 4D CT-guided protocol at our institution).

## **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

1. Operative time measured using surgical records documenting time from skin incision to completion of surgery as recorded in operative reports at the time of surgery
2. Intraoperative frozen section requirements measured using the number of frozen section pathology reports obtained during surgery at the time of surgery

### **Key secondary outcome(s)**

Diagnostic accuracy and positive predictive value of preoperative CT imaging for parathyroid gland identification, measured using comparison of preoperative CT-identified parathyroid gland count with total parathyroid gland count in final pathological report, with true positive defined as: preoperative prediction of  $\geq 4$  glands AND final pathology report showing  $\geq 4$  glands AND postoperative day 1 iPTH concentration  $< 300$  pg/dl, at preoperative CT imaging and postoperative day 1 iPTH measurement

### **Completion date**

30/06/2025

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosed with secondary or tertiary hyperparathyroidism
2. Dialysis-dependent due to end-stage renal disease (ESRD)
3. Underwent parathyroidectomy between January 2023 and December 2024
4. Underwent a primary parathyroidectomy (i.e., no previous parathyroid surgery)
5. Underwent removal of multiple parathyroid glands during the procedure

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Total final enrolment**

103

### **Key exclusion criteria**

1. Reoperation for recurrent hyperparathyroidism
2. Underwent concurrent surgical procedures
3. Had only one parathyroid gland removed during surgery

### **Date of first enrolment**

01/02/2023

### **Date of final enrolment**

30/12/2024

## Locations

### Countries of recruitment

Taiwan

### Study participating centre

Linkou Chang Gung Memorial Hospital

No. 5, Fuxing Street

Guishan District

Taoyuan City

Taiwan

333

## Sponsor information

### Organisation

Linkou Chang Gung Memorial Hospital

### ROR

<https://ror.org/02dnn6q67>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

Participant-level data will not be made available for sharing due to patient safety and institutional security concerns.

Patient Privacy Protection: Individual patient data contains sensitive medical information that could potentially compromise patient confidentiality, even when de-identified.

Institutional Data Security Policy: Our hospital's data governance policy restricts the sharing of raw clinical data to protect patient privacy and maintain institutional security standards.

Regulatory Compliance: Sharing of detailed medical records may violate local healthcare data protection regulations and patient consent agreements.

Alternative Data Access: Aggregated and anonymized summary statistics will be made available upon reasonable request for research purposes, following appropriate ethical approval and data use agreements.

**IPD sharing plan summary**

Not expected to be made available