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

Submission date
10/07/2025

Recruitment status
No longer recruiting

Registration date
14/07/2025

Overall study status
Completed

Last Edited
14/07/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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 ≥4 glands AND final pathology report showing ≥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