

# Identification of the parathyroid glands during surgery

<b>Submission date</b> 10/07/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/07/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/07/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

How to quickly and accurately identify and localize living parathyroid tissue, protect its functional integrity, and reduce the risk of intraoperative parathyroid function damage is a great challenge for clinicians and a technical challenge for researchers in the field of life and health. This study aims to develop methods to accurately identify the parathyroid glands to reduce intraoperative injury.

### Who can participate?

Patients aged 18-99 years with parathyroid disorders

### What does the study involve?

This study involves real-time detection of parathyroid glands during surgery using autofluorescence.

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

Possible benefits of participation: Can effectively prevent damage and misresection of parathyroid glands during the surgery.

The possible risks involved are that the blood stains and the protective film covering the parathyroid gland surface may prevent an accurate identification.

### Where is the study run from?

Qingdao University Affiliated Hospital, China

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

The research started on January 15, 2025 and is expected to last for 6 months.

### Who is funding the study?

1. The Shandong Provincial Science and Technology Department
2. The Qingdao Science and Technology Bureau

### Who is the main contact?

Dr Sun Jing, [sunj@sibet.ac.cn](mailto:sunj@sibet.ac.cn)Background and study aims

# Contact information

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Scientific

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# Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

## **Study information**

**Scientific Title**

Real-time detection of parathyroid glands during surgery using a highly sensitive autofluorescence-based system

**Acronym**

RDPGs

**Study objectives**

The laser-induced fluorescence detection system that utilizes the tissue's own fluorescence is more conducive to accurately identifying the parathyroid glands during surgery, thereby reducing intraoperative damage.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 28/05/2025, Medical Ethics Committee of the Affiliated Hospital of Qingdao University (16 Jiangsu Road, Shinan District, Qingdao, 266000 , China; +86 0532 82911869; wanglin@qdu.edu.cn), ref: QYFYEC2024-75

**Study design**

Observational case-control study

**Primary study design**

Observational

**Secondary study design**

Case-control study

**Study setting(s)**

Hospital, Laboratory

**Study type(s)**

Diagnostic

**Participant information sheet**

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

Accurate identification of the parathyroid glands during surgery

**Interventions**

After being enrolled, the participants underwent detection intervention using a parathyroid detector and were compared and verified with the gold standard (such as intraoperative rapid pathology or postoperative pathology results, as well as the detection results of the PTeye system). The surgical process strictly followed the methods and procedures outlined in the "Expert Consensus on Parathyroid Protection during Thyroid Surgery". The trial required the test group and the control group to simultaneously identify the suspected parathyroid tissue of the same subject, reach a conclusion on whether it was parathyroid tissue, and record the judgment results and test response times of both groups of tests, and conduct an assessment and analysis of the statistical indicators of the data information. The detection process was carried out during the surgery, and usually lasted for a few hours on the same day.

The total duration of observation is the period of intraoperative monitoring and immediate postoperative assessment, which lasts approximately 1 day; the total duration of follow-up is within 7 days after the surgery, used to assess postoperative complications (such as hypocalcemia) or other related adverse events. The entire research process, from enrollment to the last follow-up, lasts approximately 7 days.

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Fluorescence intensity value. The developed parathyroid detection instrument based on fluorescence-induced spectroscopy technology measured during each surgical procedure

**Secondary outcome measures**

Fluorescence intensity value. Fluorescence-induced laser spectroscopy technique by PTeye system during each surgical procedure

**Overall study start date**

20/12/2024

**Completion date**

05/07/2025

**Eligibility****Key inclusion criteria**

1. Thyroid diseases
2. Aged between 18 and 99

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

99 Years

**Sex**

Both

**Target number of participants**

150

**Total final enrolment**

106

**Key exclusion criteria**

Secondary hyperparathyroidism

**Date of first enrolment**

05/04/2025

**Date of final enrolment**

01/07/2025

## **Locations**

**Countries of recruitment**

China

**Study participating centre**

**Qingdao University Affiliated Hospital**

No. 59, Haier Road, Laishan District

Qingdao City, Shandong Province

China

266100

## **Sponsor information**

**Organisation**

Department of Science and Technology of Shandong Province

**Sponsor details**

No. 607, Shunhua Road, High-tech Zone

Jinan City, Shandong Province

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**Sponsor type**

Government

**Website**

<http://kjt.shandong.gov.cn/index.html>

**ROR**

<https://ror.org/01b9fvd84>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Science and Technology Bureau of Qingdao City, Shandong Province

**Alternative Name(s)**

Qingdao Science and Technology Bureau, Qingdao Municipal Science and Technology Commission,

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

China

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date**

10/10/2026

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analyzed during the current study will be provided upon request from Jing Sun, [sunj@sibet.ac.cn](mailto:sunj@sibet.ac.cn)

- Suzhou Institute of Biomedical Engineering and Technology, Chinese Academy of Sciences  
songyuxiao@sibet.ac.cn
- Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).
- Beginning 9 months and ending 36 months following article publication.

**IPD sharing plan summary**

Available on request