

Identification of the parathyroid glands during surgery

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
10/07/2025	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
16/07/2025	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
06/01/2026	Surgery	

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

Background and study aims

Contact information

Type(s)

Scientific

Contact name

Dr Jing Sun

ORCID ID

<https://orcid.org/0000-0001-6722-252X>

Contact details

Building 3, Jinan Yaogu, 100 meters west of Gangxing Third Road, Licheng District

Suzhou

China

215163

+86 18253121729

sunj@sibet.ac.cn

Type(s)

Principal investigator

Contact name

Prof Chenyu Jiang

Contact details

Suzhou Institute of Biomedical Engineering and Technology

88 Keling Road, Suzhou City, Jiangsu Province

Suzhou

China

215163

+86 13402617742

jiangcy@sibet.ac.cn

Type(s)

Public

Contact name

Dr Binghong Song

Contact details

Suzhou Institute of Biomedical Engineering and Technology

88 Keling Road, Suzhou City, Jiangsu Province

Suzhou

China

215163

+86 18253121729

songbh@sibet.ac.cn

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

Completion date

05/07/2025

Eligibility

Key inclusion criteria

1. Thyroid diseases
2. Aged between 18 and 99

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

99 years

Sex

All

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

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

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

- 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>		20/11/2025	06/01/2026	Yes	No