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Identification of the parathyroid glands during surgery

Submission date 10/07/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 16/07/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/07/2025	**Condition category** Surgery	[_] Individual participant data [X] 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.cnBackground and study aims

Contact information

Type(s)
Scientific

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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 Affilliated 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
Adult

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
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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 under liethe results reported in this article, after deidentification (text,tables,figures, andappendices).
• Beginning 9 months and ending 36 months following article publication.

IPD sharing plan summary
Available on request