INFORMED CONSENT FORM

FOR PARTICIPATION IN CLINICAL RESEARCH

Official Title:

Deep Learning-Based Intraoperative Dual-Tracer Video Analysis of Sentinel Lymph Node Mapping for Metastasis Prediction in Clinically Node-Negative Papillary Thyroid Carcinoma: A Prospective Cohort Study

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Institution:

The First Affiliated Hospital of Chongqing Medical University
Department of Breast and Thyroid Surgery
Chongqing, China 400016

Principal Investigator: Professor Xinliang Su, MD, PhD
Contact: suxinliang@21cn.com

Ethics Approval Number: 2023-322

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1. INTRODUCTION

You are being invited to participate in a clinical research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information.

Your participation in this study is entirely voluntary. You are free to decide not to participate or to withdraw from the study at any time without affecting your medical care or your relationship with your doctors.

2. PURPOSE OF THE STUDY

You have been diagnosed with papillary thyroid carcinoma (thyroid cancer). Before your surgery, imaging tests (such as ultrasound) have not shown any clear evidence of cancer spread to your lymph nodes. However, we know that some patients may have cancer in their lymph nodes that is too small to be detected by these tests.

The purpose of this research study is to:

- Compare three different methods for identifying sentinel lymph nodes (the first lymph nodes that drain from the thyroid tumor) during surgery
- Evaluate which method is most accurate in predicting whether cancer has spread to lymph nodes
- Develop computer programs (artificial intelligence) that can help doctors predict lymph node involvement during surgery

We hope that this research will help improve surgical treatment for patients with thyroid cancer in the future by helping surgeons make better decisions about which lymph nodes need to be removed.

3. STUDY PROCEDURES

If you agree to participate in this study, the following will happen:

Before Surgery:

- You will undergo standard preoperative tests including blood tests and thyroid ultrasound
- Your medical history and test results will be recorded for the study
- You will be assigned to one of three groups that use different dye methods to identify lymph nodes

During Surgery:

- You will receive your scheduled thyroid surgery

- A small amount of dye (or combination of dyes) will be injected around your thyroid tumor
- The dye will travel through your lymphatic system and help the surgeon identify sentinel lymph nodes
- For some participants, a special camera will record video of how the dye moves through the lymph system
- The sentinel lymph nodes and other lymph nodes will be removed and sent for examination
- Your surgery will proceed according to standard medical practice

The Three Study Groups:

Group 1 (ICG): You will receive indocyanine green dye, which glows under special light

Group 2 (CNs): You will receive carbon nanoparticles, which stain lymph nodes black

Group 3 (ICG+CNs): You will receive a combination of both dyes, and video will be recorded

After Surgery:

- The removed lymph nodes will be examined under a microscope
- You will receive standard post-operative care
- We will follow your recovery for 12 months
- For Group 3, computer programs will analyze the recorded video (this does not affect your treatment)

4. RISKS AND DISCOMFORTS

The dyes used in this study have been used safely in many patients. However, as with any medical procedure, there are some risks:

Risks related to Indocyanine Green (ICG):

- Allergic reactions occur in less than 0.05% of patients (very rare)
- ICG should not be used if you are allergic to iodine
- Temporary green discoloration of skin or body fluids (harmless)

Risks related to Carbon Nanoparticles (CNs):

- Temporary black staining of tissues near the injection site
- Local injection site reactions (rare)

General Surgical Risks:

These are risks of thyroid surgery in general, not specific to this study:

- Temporary or permanent changes in calcium levels (hypoparathyroidism)
- Temporary or permanent voice changes (recurrent laryngeal nerve injury)
- Bleeding
- Infection

- Scarring

Important: The dye injection and video recording used in this study are not expected to increase your surgical risks. Your surgery will be performed according to standard medical practice.

5. POTENTIAL BENEFITS

Direct benefits to you:

- The sentinel lymph node mapping may help your surgeon identify lymph nodes that need to be removed
- You will receive careful monitoring throughout the study
- There is no guarantee that you will benefit directly from this study

Benefits to society:

- The results of this study may help improve treatment for future patients with thyroid cancer
- The artificial intelligence tools developed may help surgeons make better decisions

6. ALTERNATIVES TO PARTICIPATION

If you choose not to participate in this study, you will still receive standard thyroid cancer surgery. Your medical care will not be affected by your decision.

7. CONFIDENTIALITY

Your privacy is important to us. We will protect your information as follows:

- All your personal information will be kept confidential
- Your data will be assigned a code number and stored separately from your name
- Video recordings will not include your face or other identifying features
- Only authorized research staff will have access to your data
- Published results will not identify you personally
- Data will be stored securely and protected by password

Your records may be reviewed by:

- The research team
- The Ethics Committee of The First Affiliated Hospital of Chongqing Medical University
- Regulatory authorities (if required by law)

8. COSTS AND COMPENSATION

- There is no additional cost to you for participating in this study
- The study-related dyes and procedures are provided at no extra charge
- You will still be responsible for standard medical costs not related to the study
- No payment will be provided for your participation

9. WHAT IF I AM INJURED?

If you experience any injury or adverse event related to the study procedures, you should contact the research team immediately. Medical treatment will be provided according to standard clinical

practice. Please note that participation in this study does not include compensation for any injury that may occur.

10. VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is completely voluntary. You have the right to:

- Decide not to participate
- Withdraw from the study at any time without giving a reason
- Request that your data be removed from the study (if feasible)

Withdrawing from the study will not affect your medical care or your relationship with your doctors. If you withdraw, any data collected before your withdrawal may still be used in the research unless you request otherwise.

11. CONTACT INFORMATION

If you have questions about the study:

Principal Investigator: Professor Xinliang Su, MD, PhD
Email: suxinliang@21cn.com
Phone: 023-89011876

Co-Investigator: Dr. Qian Xiao, MD, PhD
Email: Xqcq89@icloud.com

If you have questions about your rights as a research participant:

Ethics Committee of The First Affiliated Hospital of Chongqing Medical University
Phone: 023-89011876
Address: No. 1 Youyi Road, Yuzhong District, Chongqing

12. NEW INFORMATION

If any new information becomes available during the study that may affect your willingness to continue participating, you will be informed promptly.

CONSENT STATEMENT

I have read (or have had read to me) the information in this consent form. I have had the opportunity to ask questions, and my questions have been answered to my satisfaction. I understand the purpose, procedures, risks, and benefits of this study. I understand that my participation is voluntary and that I may withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I voluntarily agree to participate in this research study.

I agree to allow video recording during my surgery for research purposes (Group 3 only).

I have been given a copy of this consent form for my records.

PARTICIPANT

_____	_____
Printed Name of Participant	Date (YYYY/MM/DD)
_____	_____
Signature of Participant	Time

PERSON OBTAINING CONSENT

Printed Name	Date (YYYY/MM/DD)
Signature	Time

PRINCIPAL INVESTIGATOR (OR DESIGNEE)

I confirm that I have explained the nature, purpose, procedures, risks, and benefits of this research study to the participant. I have answered all questions to the best of my ability.

Printed Name	Date (YYYY/MM/DD)
Signature	Time

--- END OF INFORMED CONSENT FORM ---