Prospective Observational Study on the Application Effect of Electromagnetic Navigation Tip Positioning versus Traditional Intracardiac Electrogram Positioning in PICC Catheterization Patient Informed Consent Form

Informed Consent Form Version Number: 03, August 6, 2025

Medical Institution: Sun Yat-sen University Cancer Center

Principal Investigators (PIs): Hu Zeyin

Dear Patient:

You are invited to participate in a clinical study conducted by a tertiary first-class oncology hospital in Guangzhou, entitled "Prospective Observational Study on the Application Effect of Electromagnetic Navigation Tip Positioning versus Traditional Intracardiac Electrogram Positioning in PICC Catheterization". This study aims to compare the clinical application effects of two tip positioning techniques for Peripherally Inserted Central Catheter (PICC) (electromagnetic navigation tip positioning technology and traditional intracardiac electrogram positioning technology), providing reference for optimizing PICC catheterization procedures, enhancing safety and effectiveness.

Before deciding whether to participate in this study, please read the following content carefully. If you have any questions, feel free to consult the research team, and we will provide detailed answers. Participation in this study is entirely voluntary; you may refuse to participate or withdraw at any time during the study, which will not affect your regular treatment and medical services.

I. Basic Information of the Study

1.Study Title: Prospective Observational Study on the Application Effect of Electromagnetic Navigation Tip Positioning versus Traditional Intracardiac Electrogram Positioning in PICC Catheterization

2.Research Institution: A tertiary first-class oncology hospital in Guangzhou

3.Principal Investigator: [Please fill in the name of the investigator], [Please fill in the professional title, e.g., Chief Physician/Professor]

4.Study Period: October 1, 2025 to December 29, 2025 (data collection phase)

II. Study Purpose

This is a prospective observational study aiming to collect clinical data from cancer patients undergoing PICC catheterization and compare the differences between the two tip positioning techniques (electromagnetic navigation tip positioning technology and traditional intracardiac electrogram positioning technology) in the following aspects:

1.One-time success rate of PICC catheterization;

2.Accuracy of catheter tip positioning;

3.Catheterization procedure time and post-catheterization adjustment time;

4.Incidence of catheter-related complications (e.g., thrombosis, infection, catheter dysfunction) within 4 weeks after catheterization.

Through the above comparisons, this study intends to provide scientific evidence for clinically selecting safer and more efficient PICC tip positioning techniques, so as to optimize PICC catheterization processes, reduce complications, and improve patients' treatment experience.

III. Study Methods and Procedures

(I) Study Subjects

The subjects of this study are cancer patients who undergo PICC catheterization in our hospital from October 1, 2025 to December 29, 2025.

(II) Study Design

This is an observational study that does not interfere with your clinical treatment decisions. When you undergo PICC catheterization, the PICC nurse will select either electromagnetic navigation tip positioning technology or traditional intracardiac electrogram positioning technology according to clinical routine (both technologies are commonly used PICC tip positioning methods in clinical practice and have obtained national medical device registration and approval).

(III) Data Collection

The research team will collect relevant study data through the following methods, without adding additional examinations, procedures, or follow-up visits:

1. Baseline information: Including age, gender, cancer type, disease course, comorbidities, etc. (derived from your medical records);
2. PICC catheterization-related data: Positioning technology used during catheterization, one-time catheterization success, accuracy of catheter tip positioning (confirmed by chest X-ray, a routine examination for PICC catheterization), catheterization procedure time, post-catheterization adjustment time, etc. (derived from catheterization operation records);
3. Follow-up data: Incidence of catheter-related complications (e.g., thrombosis, infection, catheter occlusion or dislocation) within 4 weeks after catheterization (derived from your inpatient/outpatient follow-up records).

IV. Potential Risks and Discomforts

Participation in this study will not increase additional risks; the risks you face are consistent with those of patients undergoing routine PICC catheterization, mainly including discomforts or complications that may be caused by the PICC catheterization procedure itself, such as:

- Puncture-related: Mild pain, bleeding, hematoma, or bruising at the puncture site;
- Catheter-related: Abnormal catheter tip position (requiring adjustment or re-catheterization), catheter occlusion, dislocation, or fracture;
- Infection or thrombosis: Catheter-related infection (e.g., redness and swelling at the puncture site, fever), venous thrombosis (e.g., limb swelling, pain), etc. (The incidence is low, and medical staff will monitor and handle it in a timely manner according to routine procedures).

If you experience any discomfort after catheterization, please inform your attending PICC nurse or the research team immediately, and we will evaluate and take corresponding measures promptly.

V. Potential Benefits

Your participation in this study will not directly provide additional therapeutic benefits, but your participation will help accumulate clinical data of the two positioning technologies in PICC catheterization, providing a basis for optimizing PICC catheterization techniques, improving catheterization safety and effectiveness in the future, thereby potentially benefiting more patients.

Meanwhile, your PICC catheterization and follow-up process will strictly follow clinical routines, and the quality of medical care and nursing services will not be affected by participation in the study.

VI. Data Collection and Privacy Protection

1. Anonymization of data: All collected data will be anonymized, with unique identifiers used instead of your real name, medical record number, and other personal identifiers. Original data and identity information will be stored separately and encrypted;
2. Scope of data use: The collected data will only be used for statistical analysis of this study and

will not be used for any purpose unrelated to the study;

3. Privacy protection: Your personal information and study data will be strictly confidential and accessible only to authorized personnel of the research team. They will be stored and managed in accordance with regulations such as the *Personal Information Protection Law of the People's Republic of China* and the *Measures for the Ethical Review of Biomedical Research Involving Humans*. When publishing study results, only aggregated statistical data will be presented, without disclosing any personal identifiers that can identify you.

VII. Voluntary Participation and Withdrawal

1. Voluntary participation: Participation in this study is entirely your voluntary choice; you may refuse to participate, and this will not affect your regular treatment and medical services;
2. Withdrawal at any time: If you decide to withdraw from the study, you can inform the research team through the contact information at any time without providing a reason. After withdrawal, anonymized data already collected will no longer be included in the study analysis (stored data will be kept in accordance with regulations but will not be used for the study), and this will not affect your subsequent treatment;
3. Study termination: The research team has the right to terminate the study when necessary (e.g., if significant safety issues are found) and will inform you promptly.

VIII. Study-related Inquiries

If you have any questions, suggestions, or need help regarding this study, please contact:

- Principal Investigator: [Please fill in the name of the investigator], Contact number: [Please fill in the contact number]
- Hospital Ethics Committee: If you have questions about the ethical aspects of the study, you can contact the Hospital Ethics Committee, Tel: [Please fill in the Ethics Committee's phone number]

IX. Consent Statement

I have carefully read and understood all contents of the above *Patient Informed Consent Form*. The research team has explained to me the purpose, methods, potential risks and benefits, data privacy protection, and rights of voluntary participation of this study. I understand that participation in this study is voluntary and that I can withdraw at any time without affecting my treatment. I agree to participate in this study and authorize the research team to collect and use my relevant clinical data for this study.

Patient's Signature: _____

Date:_____

Investigator's Signature: _____

Date: _____