Cover Page

Official Title: A Prospective Study Exploring a Novel Nanoprobes (Mn/QD-SAC) for Monitoring and Protection in Flap Surgery

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Informed Consent Form

A Prospective Study Exploring a Novel Nanoprobe (Mn/QD-SAC) for Monitoring and Protection in Flap Surgery

Introduction

You are invited to participate in a clinical research study titled "A Prospective Study Exploring a Novel Nanoprobes (Mn/QD-SAC) for Monitoring and Protection in Flap Surgery." This study is conducted by the Breast Center of Hubei Cancer Hospital.

This is a prospective, exploratory study designed to evaluate the safety and biological effects of a new nanomaterial within the body, aiming to provide new methods for improving outcomes in flap surgery in the future. This study has been reviewed and approved by the Ethics Committee of Hubei Cancer Hospital. This informed consent form provides you with information to help you decide whether to participate. Your participation is entirely voluntary. Whether you participate or not, your routine diagnosis and treatment will not be affected and will always follow standard medical practices. If you agree to join the study, please review the following information.

Study Purpose

The DIEP flap breast reconstruction surgery you are scheduled to undergo is a mature technique. However, after surgery, the flap may experience partial necrosis due to blood circulation problems (ischemia-reperfusion injury). We are researching a novel nanomaterial called "Mn/QD-SAC" which, in the future, may help doctors detect blood flow issues in the flap earlier and provide protection. The purpose of this study is to collect your blood samples before and after surgery according to a set schedule. These samples will be used to test specific indicators related to inflammation, oxidative stress, and tissue damage, analyzing the body's response to surgery. This will provide key data for subsequent clinical translation.

Study Procedures

If you agree to participate in this study, in addition to the **routine examinations** required for your medical treatment, we will need to arrange for additional blood draws according to the study plan, as detailed below:

Time Point	Total Blood Volume	Test Content
Preoperative (Baseline)	10 mL	Inflammatory factors, oxidative stress indicators, baseline complete blood count, coagulation function
Postoperative 0 h (Immediate)	10 mL	Early ischemia-reperfusion response indicators (inflammatory factors, tissue damage markers, oxidative stress products)
Postoperative 6 h	10 mL	Indicators related to inflammatory peak and oxidative stress
Postoperative 24 h	10 mL	Ongoing inflammation and repair markers
Postoperative 72 h	10 mL	Indicators of inflammation resolution, repair trends, and oxidative stress recovery

The total blood volume drawn for the study will be approximately 50 mL. All blood draws will be synchronized with your clinical treatment blood draws and performed by professional healthcare staff to minimize any inconvenience. Additionally, we will collect relevant anonymized medical record data from your post-surgery period (such as clinical assessment records of flap survival) for research analysis.

Your samples and all the resulting research data will be coded and anonymized. All testing will be used solely for this study. This study will not affect your treatment

plan, surgical decisions, or postoperative care. **You will not receive any injection of the Mn/QD-SAC nanomaterial.**

Potential Benefits

This study itself will not directly alter your treatment. However, the samples and information you provide will make an important contribution to the future development of more precise strategies for monitoring and protecting flaps, potentially helping future patients in similar situations to reduce the risk of surgical complications and improve surgical success rates.

Potential Risks and Discomforts

The primary risks of this study are associated with the multiple blood draws. Each blood draw may cause brief needle-prick pain, local bruising, or, very rarely, infection or fainting (vasovagal reaction). All procedures will be strictly performed by professional healthcare staff using standard sterile techniques to minimize risks. This study **does not involve** the use of the experimental nanomaterial on you; therefore, you will not bear any potential risks associated with the material itself.

Alternative Interventions

There are no alternative interventions or treatments offered as part of this study.

Privacy

Your privacy will be strictly protected. Your personal identification information, such as your name and ID number, will not be disclosed. All research data (including all test results) will be identified only by an anonymous code and will be accessible solely by the research team under confidential conditions. Your samples and information will be used only for this research project. Any published results will not contain any information that could identify you personally.

Costs

You will not have to pay any additional costs for participating in this study. All costs associated with the blood tests and related analyses listed in the study plan **will be covered by the research project.**

Voluntary Participation and Right to Withdraw

Your participation is completely voluntary. You have the right to withdraw from the study at any time, for any reason, without any penalty. This will not affect your access to any medical services or your rights, and your relationship with your healthcare providers will not be affected. If you choose to withdraw, any samples and data you have provided will be destroyed or their use will be stopped, according to your request.

Contact Information

If you have any questions about the study or experience any discomfort during the research process, please feel free to contact our research physician.

Research Physician: _____
Contact Phone Number: _____

If you have questions regarding your rights as a research participant, you may contact the Ethics Committee of Hubei Cancer Hospital at **027-87671663.**

Statement of Consent

I have carefully read this informed consent form. The research physician has provided me with a comprehensive and detailed explanation of the study's purpose, procedures, potential risks, benefits, and privacy protections, and has answered all my questions. I fully understand that this study requires the collection of my blood samples according to the plan described above for specific tests, and that all related costs are covered by the research party. I voluntarily agree to participate in this study.

Participant Signature: _____

Date: _____ Year _____ Month _____ Day

Witness Signature (if required): _____

Date: _____ Year _____ Month _____ Day

(Note: A witness signature is required if the participant is unable to read or understand the form independently; if the participant lacks the capacity to consent, consent must be provided by a legal guardian.)

Investigator Signature: _____

Date: _____ Year _____ Month _____ Day

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