Targeted axillary dissection using carbon marking for patients with node-positive breast cancer following neoadjuvant therapy (TADCOM): a prospective, multicenter, randomized controlled trial

Informed consent

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Background

You have been invited to participate in a clinical research study conducted by the Department of Breast Surgery at the Second Affiliated Hospital, Zhejiang University School of Medicine. This study, known as the TADCOM trial, aims to explore the benefits of carbon nanoparticle suspension injection (CNSI) marking (carbon marking) in targeted axillary dissection (TAD) for patients with breast cancer following neoadjuvant chemotherapy (NAC).

The objective of this study is to address significant challenges currently faced in the surgical management of breast cancer, particularly issues related to the use of traditional tissue marker clips, such as their tendency to be lost during treatment and their high costs. By comparing the innovative carbon marking technique with conventional clip-based marking, the study seeks to establish a more reliable, cost-effective, and minimally invasive approach to axillary surgery. This could potentially transform clinical practices and enhance patient safety by providing improved visibility and stability during surgery, thereby reducing the frequency of surgical revisions and increasing the precision of lymph node dissections.

Purpose

The TADCOM trial is designed to evaluate the effectiveness and practicality of using carbon nanoparticle suspension injection (CNSI) for targeted axillary dissection (TAD) in comparison to traditional tissue marker clip-based methods. This study specifically targets patients who have undergone neoadjuvant chemotherapy (NAC) for breast cancer. The primary goal is to determine whether CNSI offers a more feasible and effective approach for marking lymph nodes during surgery, which may improve surgical outcomes and reduce the complications associated with conventional methods.

Research Flow and Participant Responsibilities

Should you choose to participate in this trial, the specific procedures you undergo will be tailored by your physician based on your medical condition. This includes the strategic placement of either carbon nanoparticle suspension injection (CNSI) or traditional tissue markers, which is intended to enhance the precision of axillary lymph node localization during your surgery.

Routine Treatments and Assessments

Alongside the trial-specific interventions, your standard treatments—including chemotherapy, radiation therapy, and endocrine therapy—will continue as per your treatment plan without any changes due to participation in this study. Additionally, you will undergo regular medical assessments necessary for your care. These assessments may include imaging exams, laboratory tests, patient satisfaction surveys, and photographic documentation of the surgical site to monitor progress and outcomes.

Participant Cooperation

If you agree to participate, it is crucial that you provide complete and accurate information about your health status throughout the study. You will also be required

to undergo all scheduled examinations and procedures, including ultrasound-guided placement of a clip or CNSI. Following the initial procedure, you will be enrolled in a 5-year follow-up program to monitor long-term outcomes and potential side effects. This follow-up is essential for assessing the effectiveness and safety of the intervention and for improving breast cancer treatment protocols.

Record Keeping and Information Management

Your doctor will maintain a detailed medical record for you, documenting all treatments, observations, and outcomes related to the trial. Strict confidentiality will be upheld in the management of your personal and health information, in compliance with medical privacy laws and ethical guidelines.

Possible Benefits of Participation

1. **Access to Innovative Treatments:** You will have the opportunity to receive Carbon Nanoparticle Suspension Injection (CNSI) for targeted axillary dissection (TAD), a cutting-edge surgical technology not broadly available outside of research environments. This method aims to improve the precision of surgical procedures for breast cancer.
2. **Enhanced Surgical Accuracy:** CNSI is specifically designed to enhance the visibility and stability of lymph nodes during surgery. This could lead to a more precise removal of cancerous nodes, potentially reducing the necessity for further surgical interventions.
3. **Reduced Risk of Complications:** The improved precision in surgical techniques may lower the risk of common post-surgical complications such as lymphedema and nerve damage. This can lead to quicker recovery times and less post-operative discomfort for you.
4. **Contribution to Medical Research:** Your participation will contribute valuable data to the field of cancer research, helping to refine surgical techniques and improve treatment outcomes for future patients.
5. **Close Medical Monitoring:** Throughout the trial, you will receive thorough

monitoring by a team of specialized healthcare providers. This close attention ensures that any changes in your health are promptly addressed, potentially leading to better management of any complications.

Risks and Discomforts

1. **Standard Surgical Risks:** Undergoing targeted axillary dissection (TAD) with either Carbon Nanoparticle Suspension Injection (CNSI) or traditional clips carries typical surgical risks, including bleeding, infection, and reactions to anesthesia.
2. **Risks Associated with CNSI:** The use of CNSI is innovative and, as such, may introduce unexpected complications. Although designed to enhance surgical accuracy, the novel nature of CNSI means that there may be unforeseen outcomes.
3. **Allergic Reactions:** There is a potential risk of allergic reactions to the carbon nanoparticles in CNSI. These reactions can vary from mild symptoms such as rash or itching to more severe conditions like difficulty breathing or anaphylaxis. While severe reactions are considered rare, the possibility remains and requires careful consideration.
4. **Post-Surgical Discomfort:** After surgery, you may experience pain, swelling, or discomfort in the axillary (underarm) area. Typically, these symptoms are temporary but may temporarily affect your daily activities.
5. **Uncertain Benefits:** While CNSI is being studied for its potential to reduce the need for additional surgical interventions and to improve surgical outcomes, such benefits are not guaranteed. It is possible that CNSI may not provide a significant advantage over conventional surgical methods for your specific condition.

Other Treatment Interventions

In this study, no additional interventions or treatments will be administered beyond those already described. All standard care, including chemotherapy, radiotherapy, and endocrine therapy, will proceed as usual without any alterations due to your participation in this study. These treatments, along with any necessary medical testing,

will be conducted according to routine clinical practices and are not part of the experimental procedures of this study. Your participation in the trial focuses solely on the evaluation of Carbon Nanoparticle Suspension Injection (CNSI) for targeted axillary dissection (TAD) and will not interfere with any other aspects of your standard medical care.

Privacy and Confidentiality

Participation in this study requires the collection and use of your personal and medical information. We are committed to maintaining the highest level of confidentiality and will implement all necessary measures to protect your privacy.

Confidentiality of Information

Your personal data, including your name, address, phone number, ID card number, and other identifiers, will remain strictly confidential. This information will not be disclosed to anyone outside of the research team without your express consent, except as required by law.

Medical Information and Research Records

Your medical results and other research data collected during this study are also confidential. These records will be stored securely and will only be accessible to authorized members of the research team. If required by law, we may be compelled to disclose some of your medical information; however, we will make every effort to protect your privacy in such circumstances.

Regulatory and Ethical Oversight

To ensure the study complies with regulatory requirements and ethical standards, authorized representatives from government regulatory bodies or the Ethics Review Committee may need to access your personal data stored at the research unit. This access is strictly controlled and is only permitted when necessary to verify compliance with research regulations.

Publication of Results

When the results of this study are published, no personal information will be disclosed. We will ensure that all published data are anonymized to prevent the identification of any participant.

Your consent to participate in this study includes your agreement to these privacy and confidentiality protections. It is important to us that you feel secure in knowing that your personal and medical information is protected throughout your participation in this research.

Fees and Costs

As a participant in this study, you will not incur any additional costs for procedures, medications, or follow-up visits associated with the trial. All trial-related expenses, including the innovative Carbon Nanoparticle Suspension Injection (CNSI) treatment, will be fully covered by the research study. Typically, this treatment is not readily available outside of research settings and could be costly. Your participation in this trial ensures access to these treatments at no cost to you.

Withdrawal and Voluntary Participation

Voluntary Participation

Your participation in this clinical trial is entirely voluntary. You are free to make an informed decision about whether to begin or continue participating in the study. You have the right to stay informed about the progress of the research and any new information that may affect your decision to remain enrolled.

Right to Withdraw

You may withdraw from the study at any time, for any reason, without penalty or loss of benefits to which you are otherwise entitled. If you decide to withdraw, your health care and benefits will not be affected. Upon withdrawal, no new data will be collected, and your previously collected data will not be used in the study analysis unless consented otherwise.

Expectations During Participation

During the study, you are expected to provide accurate information about your medical history and current health condition. You should report any discomfort or adverse effects you experience directly to the study staff. Additionally, you are expected to adhere to the study protocol as outlined by the research team.

Discontinuation by the Research Team

If at any point the research team determines that continuing in the study may pose a risk to your health or if you are seriously injured as a result of participation, the researchers will discontinue your participation to protect your safety. Similarly, if you fail to follow the study procedures or if your health condition changes in a way that no longer aligns with the study requirements, the research physician may decide to end your participation.

Assurance of Care

Regardless of your decision to continue or withdraw, you will continue to receive the appropriate medical care. Your decision will not affect the quality of care provided to you by your healthcare providers.

Contact Information

If you have any questions or concerns related to this study, or if you experience any discomfort, injury, or adverse effects during your participation, you are encouraged to contact your study physician immediately. Additionally, if you have inquiries about your rights as a participant, or the benefits to which you are entitled as part of this study, the following contacts are available to assist you:

Study Physician: [Name of the physician]

Phone Number: [Physician's contact number]

Email Address: [Physician's email]

Research Team Contact:

Contact Person: Wuzhen Chen

Phone Number: +86-13067847087

Email Address: chenwuzhen@zju.edu.cn

Institutional Review Board (IRB):

Contact Person: Lu Wang

Phone Number: +86-0571-87315215

Email Address: support@runtrial.com

These contacts are available to address any questions or concerns you may have throughout the duration of your participation in this study. It is our priority to ensure that your experience in this study is informed and comfortable.

Consent to Participate

I confirm that I have read this informed consent form, or it has been read to me, and that the study physician has explained to me in detail the purpose, procedures, risks, and potential benefits associated with participation in this clinical trial. All my questions related to the study have been answered to my satisfaction. I understand the information provided, and I voluntarily agree to participate in this clinical study.

Participant's Signature: _____

Date: _____

If the participant is unable to read:

I confirm that the information in this consent form was explained to the participant in my presence and that the participant understood and agreed to voluntarily participate.

Witness's Signature: _____

Witness's Name (Printed): _____

Date: _____

Researcher's Declaration:

I confirm that I have fully explained the nature, purpose, possible risks, and benefits of the clinical trial to the participant. I believe that the participant has understood the information provided and has voluntarily agreed to participate.

Researcher's Signature: _____

Date: _____