Evaluation of tissue marker clip guided metastatic axillary lymph node targeted dissection with methylene blue mono-tracking after breast cancer neoadjuvant chemotherapy in Chinese population: a multicenter, prospective, self-controlled study

Informed consent

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Research background:

You were invited to participate in a multicenter, prospective, self-controlled, Multicenter, self-controlled clinical study of targeted axillary lymph node dissection for breast cancer following neoadjuvant chemotherapy, chaired by the Second Affiliated Hospital of Zhejiang University Breast Surgery. This informed consent form provides you with some information to help you decide whether to participate in this clinical study. Tissue marker clamps are a kind of composite metal clamps made of titanium alloy, which can be inserted into the body to precisely locate the tiny tumor and reduce the damage of the surrounding tissue. Your participation in this study is voluntary. The study has been reviewed by the Ethics Review Committee of this research institution. You will receive the same level of medical care whether you participate in the study or not. If you agree to participate in the study, please see the following instructions.

Purpose of the study:

Objective to evaluate the efficacy and safety of methylene blue single-track axillary lymph node targeted resection (Sentinel lymph node + labeled lymph nodes)

in breast cancer patients with pathologically confirmed lymph node positive (≤3 lymph nodes, pN1) and no distant metastasis after neoadjuvant chemotherapy.

Research Flow:

If you decide to participate, your physician will determine the procedure based on your condition. The placement of a tissue marker can further improve the accuracy of axillary node localization. Your other treatments (chemotherapy, radiation, endocrine therapy) and tests are performed routinely and without any interference, these include regular or medically necessary imaging examinations, laboratory tests, satisfaction surveys, and photographs of the surgical site. Your doctor will assess your condition and establish a detailed medical record and management of all information.

If you agree to participate in this study, you will be required to provide truthful information about your health, complete the appropriate examination, the organization of the label Clamp operation and 5-year follow-up.

Possible benefits of the study:

During your follow-up, your doctor will pay close attention to your condition and the perfection of your breast shape. We hope that the information from this study will help more patients to benefit from improved quality of life after surgery. If the results of this study demonstrate the efficacy and safety of targeted axillary lymph node dissection guided by tissue marker clips after neoadjuvant chemotherapy for breast cancer, this technique will be widely used in China (and internationally) , however, more patients chose this method, and the accuracy of the location of axillary positive lymph nodes could be further improved by tissue marker insertion, this enables surgeons to make a greater contribution to the treatment of breast cancer patients and to maximize the retention and improvement of Women's quality of life, thereby benefiting more patients.

Risk and discomfort:

Regardless of whether you participate in this study, your treatment and examination will be performed according to standard clinical practice. Additional risks associated with participating in this study include: local bleeding/infection, displacement of the tag holder, skin ecchymosis, subdermal induration, and other adverse events that will be appropriately addressed by the investigators in accordance with clinical management standards.

Other treatment interventions:

There was no other intervention or treatment in this study. Other treatments (chemotherapy, radiotherapy, endocrine therapy) and testing were performed routinely and without any interference.

Privacy issues:

If you decide to participate in this study, your personal information will be kept confidential. For You, all information will be confidential. Your Medical Results and research records are highly confidential, but are subject to disclosure if legally mandated. But your personal information, including name, address, phone number, ID card number and so on, will be kept confidential and will not be disclosed without your permission. To ensure that the study is conducted in accordance with the regulations, members of the Government Administration or the Ethics Review Committee are required to have access to your personal data at the research unit if necessary. Even when the results of the study were published, all information had to be kept confidential.

Fee:

Your participation in this study will not bring you any additional medical costs, the organization of the tag clip into the operation costs are completely free for you, such as local bleeding/infection, tag clip displacement, etc. , the treatment group will be treated according to the clinical treatment standard, and the corresponding expenses will be borne by the research group.

Free Exit:

As a subject, you can keep abreast of the information and research progress related to this study, and make a voluntary decision to participate or not. You can opt out of the study at any time, regardless of injury or severity, and your data will not be included in the results. Your Medical Benefits and benefits will not be affected. If you continue to participate in the study, you will be seriously injured, the researchers will stop the study.

But during the course of the study, you will be asked to provide factual information about your medical history and current medical condition; to tell the doctor about any discomfort you experienced during the study; and if you do not follow the study plan, in the event of a study-related injury or for any other reason, the research physician may discontinue your participation in this study.

Contact:

If you have questions related to this study, or if you experience any discomfort or injury during the study, or if you have questions regarding the rights and benefits of participants in this study, you may contact your doctor.

Informed Consent to sign:

I have read this informed consent form, and my doctor has explained to me in detail the purpose, content, risks and benefits of this trial, and has answered all of my questions, i already know about this clinical study, and I volunteered for it.

Subject signature: _____

Date:

Signature of the researcher: _____

Date:

(Note: participants must be fully capacity, and witness signatures are required if they are illiterate)