A comparative study of preoperative and intraoperative carbon nanoparticles injection in patients undergoing thyroid cancer surgery

Informed Consent Form

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Informed Consent Form

Notice to Respondents

Dear Respondents:

You are invited to participate in a comparative study of preoperative and intraoperative injection of nanocarbon in patients undergoing surgery for thyroid cancer, with Liu Yang as the principal investigator, which is undertaken by the Department of General Surgery of the Second Affiliated Hospital of Xi'an Jiaotong University. This information sheet provides you with information to help you decide whether or not to participate in this scientific study. Please read this Informed Consent Form carefully and make your decision whether or not to participate in this study. Please read it carefully and ask the investigator in charge of the study if you have any questions.

Your participation in this study is voluntary. This study has been reviewed by the Ethics Committee of the Second Affiliated Hospital of Xi'an Jiaotong University.

1. Why are we inviting you to participate in the study?

Hypoparathyroidism is a common and serious complication in thyroid surgery that severely affects the quality of life of patients, especially in patients undergoing total thyroidectomy and bilateral central lymph node dissection. The key point in preventing permanent hypoparathyroidism is the identification of the parathyroid glands during the operation, which depends mainly on the physical identification of the parathyroid glands by the operator such as color, texture and surface microvascular system of the parathyroid glands. At the same time, the identification of parathyroid glands is closely related to the surgeon's surgical experience. Great care is now taken to protect the parathyroid glands from hypocalcemia during surgery. In recent years, a new type of lymphatic tracer, carbon nanoparticles have been used in parathyroid gland protection by staining lymph nodes (except parathyroid glands) black, which can help the operator to quickly identify the parathyroid glands. During the thyroid much surgeons have noticed the importance of carbon nanoparticles in the protection of the parathyroid glands, but there is still the problem of carbon nanoparticle leakage during surgery, which may interfere with the identification and protection of the parathyroid glands by accidentally staining the thyroid region black. It is well known that the use of carbon CNS is usually performed during surgery, but at our medical center we have found that preoperative injections of CNS can have

better results by reducing CNS leakage in the surgical area.

2. Why is this study being conducted?

The purpose of this study is to investigate the effect of injecting nanocarbon at different times before and during surgery in patients with bilateral papillary thyroid cancer or CN + metastases.

3. How many people will participate in this study?

Approximately 400 people will participate in this study at our institution.

4. How will the study be conducted?

This study is a randomized, double-blind, controlled design, where you have the possibility of injecting the nanocarbon preoperatively or intraoperatively, with the same dosing method in the test and control groups. For patients with preoperative injections, we will inject 0.2 ml of nanocarbon into the thyroid gland under ultrasound guidance one day prior to surgery and observe for injection-related adverse events over a 24-hour period. If the failure of preoperative injection (ectopic injection) is found during the surgery, we will perform the injection of nanocarbon again during the surgery. In the control group, the injection was performed after the thyroid gland was visualized during surgery, and the patient waited for 5 minutes after the injection before surgery. A single dose, one intramuscular injection at a time, was administered to patients with postoperative pain.

Patients in both groups did not need to come back to the hospital for follow-up and observation related to nanocarbon injection after surgery. The main focus of our experimental study is the postoperative observation of blood calcium, blood parathyroid hormone levels, and the number of lymph nodes cleared. Before you are enrolled in the study, the investigator will ask about you, record your condition, and perform screening tests.

After determining that you can participate in this study, levels of parathyroid hormones (PTHs) will be tested at three time points, including 2 weeks, 2 months, and 6 months after surgery. Postoperative hypoparathyroidism is defined as parathyroid hormone (PTHs) levels < 1.3 mmol / L after six months. patients are routinely not given calcium supplements, but patients with symptomatic hypoparathyroidism are routinely given calcium and vitamin D until PGH levels return to normal. Intravenous calcium supplementation was not routine unless severe symptomatic hypocalcemia was present. All patients were routinely treated with levothyroxine postoperatively.

5. How long will this study last?

All patients will be followed for 36-42 months. You may choose to leave the study at any time without losing any of the benefits you would have received. However, if you decide to leave the study during the study, we encourage you to talk to your investigator first. Your investigator may decide to withdraw you from the study if you develop a serious adverse event or if he/she feels that it is not in your best interest to continue participating in the study. The research organization or regulatory agency may also terminate the study during the study. However, your withdrawal will not affect your normal rights.

If you withdraw from the study for any reason, you may be asked about your participation in the study. You may also be asked to undergo laboratory tests and a physical examination if the researcher deems it necessary.

6. What are the risks of participating in the study?

The possible risks to you of participating in this study are listed below:

Possible accidents, risks and countermeasures of the proposed surgical medical program:

① Accidents and dangers that may occur during surgery, allergic reactions to drugs, anesthesia accidents, uncontrollable hemorrhage, resulting in hemorrhagic shock or even death, respiratory arrest in the center of the operation, resulting in death or irreversible brain death, depending on changes in the specific circumstances during the operation, which may lead to interruption of the surgical process or change of the surgical plan, unavoidable injuries to neighboring organs, blood vessels, nerves and other injuries, which may lead to the patient's disability, paralysis or bring about dysfunction, pressure sores on the skin outside the surgical incision due to the surgical position, the long duration of surgery, and other special needs of surgery, and other

②Possible accidents and complications after surgery: postoperative bleeding, local or systemic infections, infections around the implanted prosthesis, incision cracking, delayed closure or non-healing, organ damage and/or failure, water, electrolyte balance disorders, postoperative airway obstruction, postoperative deep vein thrombosis, if the thrombus is dislodged may be life-threatening, tumor recurrence, malignant lesions, metastasis, spread of the respiratory, cardiac arrest transient, the pre-existing diseases Deterioration, postoperative pathology report and intraoperative rapid frozen pathology examination in the results do not match the re-operation, postoperative delirium, other

③ special risks or major high-risk factors: anesthesia accidents: including

cardiac and respiratory arrest; intraoperative hemorrhage, resulting in hemorrhagic shock, acute renal failure; intraoperative depending on the specific circumstances of the determination of the surgical procedure, cervical lymph node node dissection biopsy; intraoperative damage to the proximal apparatus, such as the trachea, esophagus, etc., postoperative lymphatic fistula, tracheal fistula, esophageal fistula or stenosis, and other complications require step treatment; intraoperative damage to the recurrent laryngeal nerve or supraglottic laryngeal nerve, the Postoperative hoarseness, choking on drinking water and other complications requiring further treatment; postoperative hypoparathyroidism, hypocalcemic convulsions may be possible; postoperative asphyxia, tracheotomy is required; postoperative closed chest drainage may be possible; postoperative wound infections, lung infections, and urinary infections may be possible; postoperative recurrence, malignant transformation may be possible; intraoperative frozen pathology and postoperative paraffin pathology may be inconsistent in the results; if postoperative pathology confirms the diagnosis of malignant, it may require radiotherapy or secondary surgery; other possibilities such as: intraoperative and postoperative cardiovascular and cerebrovascular accidents.

Based on the above possible risks, we will take the following precautionary measures to maximize the patient's safety and enable the treatment process to be completed smoothly according to medical norms, as follows:

①Preoperative recognize its assessment of the patient, choose the appropriate surgical plan, complete the preoperative pick-up and perioperative treatment, and provide symptomatic treatment according to the underlying disease;

② intraoperative careful, standardized operation, close monitoring of vital signs, ready for a variety of first aid equipment, timely treatment of various situations arising during the operation;

③ Monitor the vital signs and surgical site changes closely after operation, and deal with the problems in time;

(iv) If necessary, ask the relevant laboratories to consult and assist in treatment;

⑤ Other related precautions.

Medicine is an empirical science, and there are many unrecognized areas. There are many unrecognized areas. Patients have great individual differences, and the changes of diseases are also different, so the same diagnostic and treatment methods may have different results. Therefore, any surgery may fail to achieve the expected results and may result in complications, injuries or even deterioration of the

disease. Any surgery has a high risk of diagnosis and treatment, some risks can not be foreseen and prevented by medical personnel and current medical knowledge, and physicians can not make any guarantee for the results of surgery. However, we will take good medical ethics as a guideline, strictly abide by the medical operation standard, and strive to minimize the risk to achieve the effect of surgical diagnosis and treatment.

Pre-operative injection of nanocarbon may lead to local bleeding and ectopic injection. For ectopic injections, our ultrasonographers have experience in hundreds of injections, and the injections are performed under ultrasound guidance, which can minimize the occurrence of ectopic injections. Even if ectopic injection occurs, it only results in poor lymph node visualization, which can be remedied by intraoperative injection with no adverse effects on the patient. Bleeding is a possible complication of all punctures, which can be controlled by localized pressure after injection with the smallest needles and without the risk of hemorrhage from the puncture.

Any other adverse effects of participating in the program will be managed appropriately. If you experience any discomfort during the study, or any unforeseen circumstances, whether or not related to the study, you should notify your investigator, who will make a determination and provide appropriate medical/other treatment.

You will be required to follow up at the Second Affiliated Hospital of Xi'an Jiaotong University on time during the study period for some tests, which will take up some of your time and may cause you trouble or inconvenience.

7. What are the benefits of participating in the study?

Direct Benefits: If you agree to participate in this study, you may receive direct medical benefits. Intra-thyroid nanocarbon injections are necessary for thyroid surgery, and many studies have shown that preoperative injections of nanocarbon are more effective than intraoperative injections in protecting the parathyroid glands and tracing the lymph nodes. Ultrasound-guided injections will be provided at no cost to the patient if preoperative injections are given.

Potential benefits: Your participation in this study will help to obtain scientific data that will provide important evidence for disease diagnosis and treatment, biomedical science research, etc., and will have a certain social value.

8. How will the results of the study be used and how will my privacy be protected?

If you decide to participate in this study, your participation in the study and your

personal information during the study will be kept confidential. Your blood/urine specimen will be identified by the study number and not by your name. Information that identifies you will not be shared with anyone outside the research team unless you give your permission. All study members and the research organization are asked to keep your identity confidential. Your file will be kept in a locked filing cabinet and will be accessible only to the researcher. To ensure that the research is conducted in accordance with the regulations, members of the government administration or the ethical review board are required to have access to your personal data at the research unit when necessary. No information about you will be disclosed when the results of this study are published.

9. What are the costs of the products used in the study and related tests?

We will assess your condition prior to the surgery. If routine use is required during the surgery, you will need to purchase the products yourself, and this item is not free of charge. On this basis you can decide whether or not to participate in this study. If you decide to participate in this study and need a pre-operative injection of nanocarbon, ultrasound-guided injections will be provided free of charge to the patient. Routine treatments and examinations required for other diseases that you have at the same time will not be covered free of charge.

10. What is the compensation/reimbursement in case of injury?

In the event of an injury related to the study, you may receive free treatment from the Second Affiliated Hospital of Xi'an Jiaotong University or compensation in accordance with relevant Chinese laws.

11. What are your rights?

Your participation in the study is voluntary. If you decide not to take part in the study, it will not affect the other treatments you are entitled to. If you decide to participate, you will be asked to sign this written informed consent form. You have the right to withdraw from the trial at any time during any stage of the trial without being discriminated against or treated unfairly, and your rights will not be affected.

12. What are the precautions?

As a subject, you are required to provide truthful information about your medical history and current physical condition; to tell the investigator about any discomfort you notice during this study; not to take restricted products, foods, etc., that the investigator has told you about; and to tell the investigator whether or not you have been involved in any other studies recently, or are currently involved in any

other studies.

Informed Consent Signature Page

Informed Consent Statement:

I have been informed about the purpose, background, process, risks and benefits of this study.

I was given ample time and opportunity to ask questions and the questions were answered to my satisfaction.

I have also been told who to contact when I have questions, want to talk about difficulties, concerns, suggestions for the study, or want to get further information or help with the study.

I have read this informed consent form.

My participation in this study is voluntary.

I have been informed that I may choose not to participate in this study or withdraw at any time without discrimination or retaliation by notifying the researcher, and that none of my rights or interests will be affected as a result.

The researcher may terminate my continued participation in this study if I need other interventions, if I do not comply with the study plan, if a study-related injury occurs or for any other reason.

I will receive a signed copy of the Informed Consent Form with my signature and the investigator's signature.

Subject's name: _____

Contact number: _____

Subject's signature: _____

Date: _____ Year _____ Month _____day

I have accurately communicated this document to the subject and he/she has accurately read this informed consent form and had the opportunity to ask questions.

Investigator's name: _____

Contact phone number: _____

Investigator's signature: _____

Date: _____ Year _____ month _____ day

(Note: Witness signature is required if the subject is illiterate and fashion, and proxy signature is required if the subject is incapacitated.)