Participation in Clinical Research

Prospective observational study of elective neck dissection for clinical N0 tongue cancer

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Introduction

This research is clinical research conducted to improve the cure rate of oral cancer. Clinical research is medical research conducted on human subjects for the purpose of improving methods of disease prevention, diagnosis and treatment, understanding the causes of disease, and improving the quality of life of patients. Nagasaki University Hospital has established the "Nagasaki University Hospital Clinical Research Ethics Committee" to conduct rigorous review of each clinical research. This clinical research is conducted with the approval of the Ethics Committee and the hospital director.

Please note that this clinical research is not a so-called "clinical trial," a clinical study conducted by a pharmaceutical company or other organization to investigate the safety and efficacy of a new drug and obtain approval from the Ministry of Health, Labor and Welfare. You are free to decide whether or not to participate in this study. If you choose not to participate in the study, we will continue to provide the best treatment for your situation.

This study is to determine whether prophylactic neck dissection is effective during resection of tongue cancer that is clinically free of cervical lymph node metastasis (this is called cN0).

1. Description of the Study

In this study, we will prospectively observe the postoperative course of patients who have undergone surgery for tongue cancer with clinically no cervical lymph node metastasis (this is called cN0), with or without prophylactic neck dissection, for 3 years, and examine changes in their general condition in a multicenter setting.

Cervical dissection is a surgical procedure in which cervical lymph nodes suspected of cancer metastasis are removed in one lump with surrounding tissues to thoroughly dissect the neck. Tongue cancer tends to metastasize to cervical lymph nodes, and it is known that 30-40% of patients with early-stage tongue cancer have latent lymph node metastases that are not clinically evident at the time of initial diagnosis but become evident later. In such cases, prophylactic cervical dissection has been reported to improve outcomes (specifically, the 3-year survival rate increased from 67.5% to 80%), but it is not known whether cervical dissection is performed only when it is truly necessary. Unnecessarily performing this surgery can lead to difficulty in lifting the hand, skin hypoesthesia, and a decreased quality of life (QOL). Currently, it is difficult to accurately predict potential cervical lymph node metastases, and the decision to perform prophylactic neck dissection is still unclear.

This study is a clinical research study in a form that is consistent with actual clinical practice, in which prophylactic cervical dissection will be indicated and curative treatment will be performed using the same judgment as before after enrollment in the clinical research study, followed by a uniform follow-up.

2. Research Methods

Research will be conducted at our hospital on patients 20 years of age or older who have undergone surgery for tongue cancer without cervical metastasis from the date of approval by the hospital director of Nagasaki University Hospital to October 31, 2022.

Clinical data necessary for this study will be extracted from medical records and laboratory findings, anonymized so that individuals cannot be identified, and registered at the Data Center (Clinical Research Support System, Clinical Research Center, Shinshu University Hospital). Data collected from the designated training facilities of the Japanese Society of Oral Oncology and others (69 facilities) participating in this study will be compiled. Endpoints will include postoperative survival, postoperative recurrence-free period, and changes in quality of life (QOL) before and after surgery.

3. Consent Form

If you are willing to participate in this clinical study, you will be asked to sign a "Consent Form" in person. We will provide you with this form, and we hope that you will read it carefully and consider it carefully.

4. Anticipated Research Outcomes

In tongue cancer without cervical metastases, it may be possible to identify patients with potential lymph node metastases who truly need prophylactic neck dissection. It may also clarify the extent to which prophylactic cervical dissection results in a decreased quality of life.

5. Expected benefits of this research

It allows prophylactic neck dissection to be performed only in patients with tongue cancer who really need it with latent lymph node metastasis, eliminating the need for unnecessary neck dissection.

6. Study duration and number of expected participants

This study will run from the date of approval by the hospital director of Nagasaki University Hospital until October 31, 2026. A total of approximately 800 people are expected to cooperate in this study from the designated training facilities of the Japanese Society of Oral Oncology and others that are participating in the study.

Of these, Nagasaki University Hospital plans to cooperate with 40 patients.

The study may be terminated when the objective of the study has been achieved before the planned number of patients or the planned period is reached, or when there are instructions to change the implementation plan, etc., and it is deemed difficult to accept these instructions.

7. Disclosure of Research Results

If you wish to see the results of the study, please contact your doctor or the principal investigator. Depending on the time of the research, we may not be able to show you the results. Basically, we will only show the results to you. If a person other than the patient himself/herself requests to see the results, we will show them only to a "surrogate or immediate family member" as necessary.

8. The cost of treatment must be co-paid in accordance with the insurance system.

Patients will not be asked to pay for any special testing or other costs themselves. Therefore, although some co-payment will be incurred, as in the case of regular treatment, including consultations and examinations, participation in this study will not result in higher costs.

9. Conflicts of Interest

This clinical research is being conducted as a physician-led independent study. There are no problems regarding financial benefits or other related interests from companies or organizations that may have a potential conflict of interest, as the principal investigator and research assistants of this research have been reviewed by the Conflict of Interest Review Committee of Nagasaki University Hospital.

10. Response to Serious Health Hazards

This clinical study has been carefully planned based on reports to date. However, in the unlikely event that a serious health hazard occurs as a result of participation in this clinical research, appropriate measures, including necessary treatment, will be taken immediately.

Such treatment will be provided by insurance in accordance with general medical treatment. No compensation will be paid for participation in this clinical study.

11. Protection of your human rights and privacy

The following considerations are made to protect your human rights.

1) This clinical research will be conducted in accordance with the "Guidelines for Conducting Clinical Trials (Japanese Association for Cancer Therapy)," which are designed to protect your human rights. These guidelines are almost the same as the "Standards for Conducting Clinical Trials" that must be followed when conducting clinical trials for new drugs that have not been

approved by the Ministry of Health, Labor and Welfare (the purpose is to "ensure the scientific quality and reliability of the results of clinical research while protecting the human rights, safety and welfare of the subjects"). guidelines for the development of new treatments for cancer.

2) You are free to decide whether or not to participate in this clinical research. If you do not consent, you will not be treated unfavorably.

3) Even if you agree to participate in this clinical study, you are free to withdraw your consent to participate in this clinical study at any time during the treatment period without any prejudice. If you wish to do so, please submit a withdrawal of consent form signed by you to the research staff, or notify us orally. You will not be treated unfavorably in any way if you do not participate in the clinical research.

4) The content of this clinical research plan is subject to scientific and ethical review and approval by the Nagasaki University Hospital Clinical Research Ethics Committee, which was established to protect your human rights, and will be conducted with the permission of the hospital director.

5) We will promptly inform you of any new information that we think is important for you to know about this clinical research.

6) We will take great care to protect your privacy. Your medical records may be accessed by parties involved in this clinical study (including outside parties) to ensure that the clinical study is being conducted properly, but all personal information will be kept confidential. In addition, some of the results of this clinical research and test results may be published in medical papers or as part of materials submitted to the Ministry of Health, Labor and Welfare, but your personal information, including your address, name, and telephone number, will be kept confidential.

7) If you have any questions about this clinical research or your rights, please contact your attending physician or the responsible physician.

12. Handling of information obtained in this study

(1) Handling of information

Since this is a multicenter collaborative study, your information obtained in this study will be provided to the Clinical Research Support Center of Shinshu University Hospital, which is the data center. Your information will be provided to the Center's clinical research support system via the Internet with an identification number attached.

(2) Storage of information

Information obtained in this research will be stored in the Clinical Research Support System of the Clinical Research Support Center of Shinshu University Hospital until at least the end of the research, but will be kept as long as possible after this period.

When disposing of the information, sufficient care will be taken to ensure that personal information is not leaked to outside parties.

13. Clinical Research Results and Presentations

The results of this clinical research will be made public in the form of presentations at scientific meetings and publications in specialized journals, but will never be presented in a way that identifies individuals..

14. Study implementation system

Research Organization
Principal Investigator: Masahiro Umeda (Professor, Department of Oral Oncology, Nagasaki University)

Principal Investigator (Data Management): Hiroshi Kurita (Professor, Department of Dental and Oral Surgery, Shinshu University School of Medicine)

Research Secretariat: Soichi Yanagimoto (Lecturer, Department of Oral Oncology, Nagasaki University)

Data Center: Clinical Research Support Center, Shinshu University Hospital

Research participating facilities: Training facilities designated by the Japanese Oral Tumor Society

To be kept by the hospital, (copy) for patients
ver. 2.0

Consent form

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Items to be explained

1. **Description of the Study**
2. **Research Methods**
3. **Consent Form**
4. **Anticipated Research Outcomes**
5. **Expected benefits of this research**
6. **Study duration and number of expected participants**
7. **Disclosure of Research Results**
8. **The cost of treatment must be co-paid in accordance with the insurance system.**
9. **Conflicts of Interest**
10. **Response to Serious Health Hazards**
11. **Protection of your human rights and privacy**
12. **Handling of information obtained in this study**
13. **Clinical Research Results and Presentations**
14. **Study implementation system**

[Signature of researcher] I explained the study to the patient.

Date of explanation:
Name of explainer: (signature)

[Patient's signature]

I have received an explanation of and understand the above items, and agree to participate in this study of my own free will and accord. I will receive a copy of the patient handbook and this consent form.

Consent Date:
Patient's name: (signature)