Patient Informed Consent

Protocol Name: The strategy of neoadjuvant or induction chemotherapy followed by surgery for operable small cell lung cancer
Protocol number: NA

Informed consent version number: 2.0, Version date: July 10, 2023

Sponsoring institution: Ruijin Hospital, Shanghai Jiao Tong University School of Medicine

Participating institution: Affiliated First People's Hospital，Shanghai Jiao Tong University School of Medicine
Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine
Huadong Hospital, Fudan University School of Medicine

Primary sponsor: Hecheng Li, Department of Thoracic Surgery

You will be invited to participate in a clinical study. This informed consent form provides you with information to help you decide whether to participate in a clinical study. Please read the informed consent form carefully and address any questions to the study investigators.

What is the background and purpose of the study？

Lung cancer is one of the most common malignant tumors worldwide and the leading cause of death among all malignant tumors. In recent years, with the gradual development of targeted therapy, immunotherapy and other treatments, the overall survival of patients with lung cancer has been significantly improved. However, the late stage of lung cancer at the time of diagnosis often makes patients only accept pneumonectomy, which leads to a higher postoperative complication rate than lobectomy, poor quality of life, and loss of the opportunity to continue adjuvant therapy, which affects the prognosis.

A number of retrospective studies have shown that patients after pneumonectomy face higher perioperative complications and mortality, and may suffer from impaired long-term survival and poor quality of life due to loss of adjuvant therapy or non-tumor factors. At present, a number of studies on neoadjuvant or induction therapy have shown that some patients have significant tumor regression after treatment. There has been a clinical precedent of deciding the operation method according to the tumor stage and local invasion status after drug treatment. However, there is still a lack of evidence-based medical evidence to show the short-term and long-term effects of surgery in this group of people, so this study is for this purpose.

You are invited to participate in this clinical study, which will prospectively explore the feasibility and long-term effect of reducing the surgical scope after neoadjuvant or induction therapy for operable non-small cell lung cancer, and lay the foundation for further research and clinical application.

What do I need to cooperate with if I participate in the study？

This study is a prospective observational clinical study. We expect to enroll 50 patients who will receive neoadjuvant/induction chemotherapy without treatment and then evaluate the feasibility of radical resection of lung cancer based on clinical data after multidisciplinary discussion. If you agree to participate in the study, we will

number you and create a medical record.

Processing of biological samples and information after the end of the study: The retained clinical data and other data will be used for future research with your consent.

As a research subject, you are required to provide a truthful account of your medical history and current medical condition; Tell the research physician about any discomfort you have experienced during the study; And do not take restricted medications such as Glucocorticoids and other immunosuppressants. Tell the research physician if you have been involved in other recent studies or are currently involved in other studies.

Is there any risk of research?

For you, all information will remain confidential.

Radical resection of lung cancer has been widely carried out in thoracic surgery, including pneumonectomy, bilobectomy, lobectomy or segmentectomy, etc. The common potential risks are mainly perioperation-related complications, including intraoperative or postoperative bleeding, persistent pulmonary air leakage, pulmonary infection, pleural effusion, etc. Severe complications may lead to death.

You may receive free treatment and/or compensation for any damages related to this clinical study.

How will participating in the study help me ?

The testing of your specimens may help to make a diagnosis of the disease, may provide necessary advice for your treatment, or may provide useful information for the study of the disease. New surgical treatment methods may help maintain general health status, improve the therapeutic effect of adjuvant drugs, and provide useful information about the prognosis of the target population.

Is there any cost or compensation for participating in the study ?

Cost: All patients who participated in the study are required to pay the corresponding costs of drugs and surgery by medical insurance or self-payment.

Reimbursement: All patients will receive one-stop treatment from thoracic surgery, radiotherapy, oncology, and other multidisciplinary departments, followed by dedicated personnel to complete the whole program management, but will not receive any compensation or subsidy for participating in the study.

What about participating in research and being harmed ?

You will receive free treatment and/or compensation for any damages associated with this clinical study.

Is my information confidential?

If you decide to participate in this study, your participation in the study and your personal data in the study will be kept confidential. Your biospecimens will be identified by the study number, not by your name. Information that could identify you will not be disclosed to members outside the research team unless your permission is obtained. All study members and study sponsors are asked to keep your identity confidential. Your files will be kept in locked filing cabinets for researchers' access only. To ensure that the study is conducted in accordance with the regulations, if necessary, the government administration or members of the ethical review committee are allowed to access your personal data at the research unit according to the regulations. No personal information about you will be disclosed

when the results of this study are published.

Do I have to attend ?

You may choose to participate or not participate in the study, or at any time notify the investigator to withdraw from the study, your data will not be included in the study results, and any of your medical treatment and benefits will not be affected.

Your participation in the study may be terminated by the study physician if you require additional treatment, or if you do not adhere to the study plan, or suffer a study-related injury, or for any other reason that continued participation may increase the risk of harm to your participation in the study.

Who should I contact for more information?

You will be kept informed of study-related information and progress, and we will keep you informed of new study-related safety information. If you have any questions related to this study, or if you have any discomfort or injury during the study, or if you have any questions about the rights and interests of the study participants, you can contact Dr. Yin Zhengxin at 18121263257.

This study has been reviewed by **the Human Research Ethics Committee of Ruijin Hospital, Shanghai Jiao Tong University School of Medicine**. If you have any questions or appeals regarding the rights and health of participating in this study, you can contact the Ethics Committee of the Institute at 54661789; Contact: Mr. Wang.

Informed Consent Signing Page

I have read this informed consent form.
I had the opportunity to ask questions and all questions were answered.

I understand that participation in this study is voluntary.

I can choose to participate or not to participate in the study, or I can withdraw at any time after informing the investigators without facing discrimination or retaliation, and my medical treatment and rights and interests will not be affected.

The study physician could terminate my participation in the study if I needed additional treatment, if I did not adhere to the study plan, or if I suffered a study-related injury or for another reason that my participation would increase my risk of harm from the study.

I will receive a copy of the signed Informed consent form.

Subject Name: _____

Signature of subject: _____

Date: _____Year_____Month____Day

Name of legal representative:_____

Signature of legal representative: _____

Date: _____Year_____Month____Day

Name of Witness:_____

Signature of Witness: _____

Date: _____Year_____Month____Day

(Note: Witness signature is required if the subject is illiterate, legal representative signature is required if the subject is incapacitated/limited)

I have accurately informed the subject of this document and asked him/her to read the informed consent form carefully and answer the questions or concerns raised.

Investigator's Name: _____

Investigator's Signature: _____

Date: _____Year_____Month____Day