Informed Consent Form

Epidemiology of Abdominal Aortic Aneurysm With Concomitant Primary Lung Cancer

Date: January 10th, 2025

Informed Consent Form

Part I. Information for Respondents

We are going to conduct an Epidemiology of Abdominal Aortic Aneurysm With Concomitant Primary Lung Cancer. Your situation may meet the inclusion criteria for this study. Therefore, we would like to invite you to participate in this study. This informed consent form will introduce you to the purpose, steps, benefits, risks, inconveniences or discomforts of the study. Please read carefully and make a careful decision on whether to participate in the study. When the researcher explains and discusses the informed consent form to you, you can ask questions at any time and ask him/her to explain any areas you do not understand. You can discuss with family, friends, and your doctor before making a decision.

If you are currently participating in other clinical studies, please inform your research doctor or researchers.

The project leader of this study is Dr. Qing Kaixiong, from the Department of Vascular Surgery at the First Affiliated Hospital of Kunming Medical University. The funding for this study is from the National Natural Science Foundation of China.

- Why was this study conducted?

1. research purpose： This study collected detailed basic information, lifestyle habits, past medical history, and laboratory

indicators from 2000 outpatient patients with primary lung cancer for data analysis and long-term follow-up. The study analyzed the related factors of lung cancer complicated with AAA, providing direct scientific evidence to better guide lung cancer patients in screening for AAA, identifying common high-risk factors for lung cancer patients complicated with AAA, providing clinical guidance for the prevention of AAA, and reducing the risk of AAA rupture. The research results are of great significance for the subsequent treatment and prognosis of lung cancer patients, as well as improving the long-term survival rate of lung cancer patients. They will also provide scientific basis and clinical guidance for the screening and prevention of AAA in lung cancer patients. Early detection and treatment of AAA can reduce the risk of AAA rupture, greatly improve the prognosis of lung cancer patients with AAA, and enhance their quality of life.

2. Brief Summary: Retrospective clinical case studies in recent years have shown that most cases of lung cancer and abdominal aortic aneurysm (AAA) are detected at the same time and that there is a wide variation in the prevalence of AAA in patients with primary lung cancer reported in the literature, with some papers suggesting as high as 11%, suggesting that there may be a relationship between the prevalence of the two diseases. However, its exact incidence and mechanism are unknown. Accurate prevention of AAA in patients with primary lung

cancer requires more in-depth studies. To solve the above problems, a multi-center prospective epidemiological investigation and mechanism study on the association of AAA in primary lung cancer combined has become particularly urgent. The results of the study will be of great significance for the follow-up treatment and prognosis of lung cancer patients as well as the improvement of long-term survival rate of lung cancer patients, and will also provide scientific basis and clinical guidance for the screening and prevention of AAA in lung cancer patients.

- Who will be invited to participate in the study?

The research subjects are patients diagnosed with primary lung cancer at the Third Affiliated Hospital of Kunming Medical University and the First Affiliated Hospital of Kunming Medical University from 1st October 2022 to 30 st April 2025.

- How many people will participate in this study?

The expected sample size is about 2000 people, and the age of patients is 20-90 years old.

- How was the study conducted?

The research subjects are patients diagnosed with primary lung cancer at the Third Affiliated Hospital of Kunming Medical University and the First Affiliated Hospital of Kunming Medical University from 1st October 2022 to 30 st April 2025. The expected sample size is about

2000 people, and the age of patients is 20-90 years old. Collect detailed epidemiological data and long-term follow-up data, conduct statistical analysis, and conduct epidemiological investigations.

Inclusion criteria:Patients diagnosed with primary lung cancer through clinical or pathological. examination

Exclusion Criteria:Patients diagnosed with primary lung cancer who refuse to undergo abdominal aortic imaging screening.

Epidemiological data collection:

1. Basic Information: name, gender, ethnicity, age, height, weight, hometown, occupation, education level, ID card, phone number, and medical record number.

2. Behavioral Life Information： Whether smoking, smoking index, alcohol consumption, alcohol content and quantity consumed, history of exposure to asbestos products, dietary habits, and history of dust exposure.

3. Past medical history and family genetic history: Presence of hypertension, degree of hypertension, blood pressure control medications, and blood pressure control; diabetes mellitus, blood glucose control medications, and blood glucose control; hyperlipidemia, elevated lipid composition, lipid control medications, and lipid control; urologic disorders; family history of vascular disorders; and family history of oncologic disorders.

4. Laboratory information: Blood pressure, fasting blood glucose, glycosylated hemoglobin Total cholesterol (TC), triglyceride (TG), high-density lipoprotein-cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C).

5. Follow-up information:

（1）Information related to primary lung cancer: types of lung tumors (squamous cell carcinoma, adenocarcinoma, small cell/neuroendocrine/other); Staging of lung tumors (stages I, II, III, IV); CNM staging; Differentiation results of lung tumors; Immunohistochemical staining results; Tumor markers (outliers); Tumor genes (outliers); The treatment methods for lung tumors (surgery, radiotherapy, chemotherapy, molecular targeting, immunity, biological therapy, neoadjuvant chemotherapy); Surgical time and bleeding volume.

（2）Information related to abdominal aortic aneurysm: whether it is complicated with abdominal aortic aneurysm; Is there a concomitant iliac artery aneurysm; Whether to undergo surgical treatment; Surgical treatment methods (endovascular repair of abdominal aortic aneurysm, open surgery); Surgical time and bleeding volume.

（3）Patient prognosis: last follow-up time, time of lung tumor recurrence, whether death occurred, and cause of death.

- How did participation in the study affect the respondents'

daily lives?

When deciding whether to participate in this study, please carefully consider the possible impact of the examinations and follow-up listed above on your daily work, family life, etc. If you have any questions about the issues, steps, and laboratory tests involved in epidemiological investigations, you can consult us.

During the data collection process, please think carefully and answer carefully. There is no right or wrong answer; Your answer is for research purposes only and will strictly adhere to confidentiality principles. However, your truthful answer will be a prerequisite for our objective research. Thank you for your trust and support!

- Risks and adverse effects for respondents participating in this study?

Your research doctor will ask questions about your basic information, behavioral and lifestyle factors, past medical history, and family genetic history. Your answers are for research purposes only and will strictly adhere to confidentiality principles. This study requires the collection of relevant laboratory data. If you have any questions about the laboratory examination content, please feel free to consult us at any time.

This project only involves collecting epidemiological data and long-term follow-up data of the respondents, and there are no obvious

adverse reactions or serious complications for you. We will explain to you the process of participating in this project, and patiently answer any questions you may have during the period. Your consent is fully required before proceeding.

- Possible benefits for subjects participating in this study?

This study is a non-interference experiment, and participating in this study will not incur any additional costs. We require your cooperation in collecting epidemiological data and long-term follow-up data. Participating in this study will screen for abdominal aortic aneurysm for you. If found, we can provide you with treatment plans and promote medical knowledge related to abdominal aortic aneurysm, which will help you decide on subsequent treatment, improve prognosis, and improve quality of life. At the same time, the development of this project will identify high-risk factors for primary lung cancer combined with abdominal aortic aneurysm, and explore their mechanisms. The research results are of great significance for the subsequent treatment and prognosis of lung cancer patients, as well as improving their long-term survival rate. It will also provide scientific basis and clinical guidance for the screening and prevention of abdominal aortic aneurysm in lung cancer patients, benefiting more primary lung cancer patients, increasing their awareness of abdominal aortic aneurysm screening, and benefiting the entire society.

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- Is it mandatory to participate and complete this study?

Whether you participate in this study is entirely voluntary. If you are unwilling, you can refuse to participate, which will not have any negative impact on your current or future healthcare. Even if you agree to participate, you can change your mind at any time and inform the researchers to withdraw from the study. You will not be discriminated against or retaliated against for withdrawing from the trial, nor will it affect your access to normal medical services. When you decide not to participate in this study, we hope you can inform your research doctor in a timely manner, who can provide advice and guidance on your health condition.

The sponsor or regulatory agency may also terminate this study during the research period. If there is an early termination of this study, we will notify you promptly, and your research doctor will provide suggestions for your next treatment plan based on your health condition.

For respondents who withdraw midway, for safety reasons, we have a final follow-up plan, and you have the right to refuse. If you discover new information related to your health and rights after exiting, we may contact you again.

After you exit, the researchers will closely preserve your relevant information until it is finally destroyed, during which time they will not continue to use or disclose this information. But in the following rare

cases, researchers will continue to use or disclose your relevant information, even if you have withdrawn from the study or the study has ended. These situations include: removing your information will affect the scientific validity of research results or the evaluation of data security; Provide some limited information for research, teaching or other activities (this information will not include your name, ID card number, or other personal information that can identify you); When schools and government regulatory agencies need to supervise research, they will require access to all research information, including relevant information about your participation in the research at that time.

- Cost of participation in the study

This project is a non-interference experiment, designed only for epidemiological data collection, long-term follow-up data collection, and blood specimen collection, and will not increase your additional treatment costs. If you have any questions, please contact us in a timely manner, and we will patiently answer your questions.

- How to deal with research related injuries?

When your health condition is harmed due to participating in this study, please inform the researcher (Dr. Qing Kaixiong 15908855311), and we will take necessary medical measures. If compensation is involved, it will be in accordance with relevant laws and regulations in China.

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- What do I need to do if I participate in the study?

✧ Provide accurate past medical history and current medical information.

✧ Tell the research doctor about any health issues you may have during the study period.

✧ Follow the guidance of researchers and research doctors.

✧ You can always inquire if there are any unclear areas.

- Will subjects' personal information be kept confidential?

If you decide to participate in this study, your participation and personal information during the study will be kept confidential. Your blood specimen will be labeled with the study number number instead of your name. Information that can identify you will not be disclosed to members outside of the research team unless your permission is obtained. All research members and sponsors are required to keep your identity confidential. Your file will be stored in a locked filing cabinet for researchers to access only. To ensure that the research is conducted in accordance with regulations, if necessary, members of government regulatory agencies or ethics committees may access your personal information at the research institution in accordance with regulations. When this research result is published, no personal information will be disclosed.

- If there are any problems or difficulties, who should I

contact?

If you have any questions related to this study, please contact Dr. Qing Kaixiong at 15908855311; Dr. Zhu Qian, contact number 15191066760.

If you have any questions related to the rights and interests of the subjects, you can contact the Ethics Committee of the First Affiliated Hospital of Kunming Medical University at 0871-65328584.

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Part II Informed Consent Signature Page

Subject Informed Consent Statement：

I have been informed of the background, purpose, steps, risks, and benefits of the epidemiological investigation on the association between primary lung cancer and abdominal aortic aneurysm. I have enough time and opportunities to ask questions, and I am very satisfied with the answers to the questions. I was also informed who to contact when I have questions or want further information. I have read this informed consent form and agree to participate in this study. I know that I can withdraw from this study at any time without any reason during the research period. I was informed that I will receive a copy of this informed consent form, which includes the signatures of myself and the researcher.

Subject's signature: Date:

Signature of legal representative: Date:

Relationship with subjects:

I confirm that the information in the informed consent form has been correctly explained and understood by the subject and/or their legal representative. The subjects voluntarily agreed to participate in this study.

Signature of fair witness: Date:

Date: January 10th, 2025

Informational statement from the researcher：

I have informed the subject (and their legal representative) of the research background, purpose, steps, risks, and benefits of the epidemiological investigation and mechanism research project related to primary lung cancer complicated with abdominal aortic aneurysm. I have given him/her sufficient time to read the informed consent form, discuss with others, and answered his/her questions related to the research; I have informed the subject of their contact information when encountering problems; I have informed the subject (or legal representative) that he/she may withdraw from this study at any time during the study period without any reason.

Signature of researcher: Date:

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