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The Informed Consent of the Cohort Study for Bronchial Asthma in China

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Informed consent

Subject initials_____

Code_____

You have been invited to participate in the program "Construction of Clinical Study Resources-Bronchial Asthma Cohort". Please read this informed consent form carefully and make a careful decision whether to participate in this study. Your participation is completely voluntary. You must sign the informed consent before participating in clinical studies. You can ask about what you do not understand when the doctor or investigator discusses the informed consent with you. We encourage you to talk with your families and friends before making the decision. You have the right to refuse, or withdraw from the study at any time, which is of no punishment or loss of your rights. Please tell your investigating doctor or investigators if you are participating in other studies. The study background, objective, process and other important information are as follows.

1. Background

Bronchial asthma (asthma) is a common chronic airway disease worldwide, affecting 1-18% of the global population. According to the global burden of disease (GBD) study in 2015, there are about 358 million asthma patients in the world, and 400,000 people die of asthma every year. According to the Chinese China pulmonary health (CPH) survey, the prevalence of asthma in Chinese people aged 20 and above is 4.2%, and the total number of patients is 45.7 million, of which about 26.2%, or 13.2 million patients, have developed irreversible airflow limitation. The above data show that asthma has become a public health and health care problem that needs to be seriously faced and solved in China.

Asthma is a heterogeneous disease whose etiology, pathogenesis, and response to existing standardized therapies vary from person to person, requiring identification of its phenotype and endotype. The study of the phenotype and endotype of asthma is helpful to the diagnosis, management and individualized treatment of asthma.Therefore, this study intends to establish an asthma cohort study, construct an information network platform system and a biological specimen bank for asthma

cohorts, establish clear follow-up standards and norms, observe the outcome of asthma, and explore biomarkers for predicting the outcome of asthma.

2. Objective

The study is to observe disease outcome in asthma and identify prognostic biomarkers for the disease outcome.

3. Process

3.1 How many people will participate in the study?

Approximately 400 people will participate in the study and will be invited to attend a more than two-year follow-up.

3.2 Steps

If you agree to participate in this study, please sign this informed consent.

Before participating in the study, your doctor will ask about your medical history and then record it, and you will have a pulmonary function test, and chest imaging test.

You will then have a baseline visit if you are recruited.

During the baseline visit, the doctor will ask about your basic information, smoking history, occupation, medical history, respiratory symptoms, treatment, etc. You will also be required to complete questionnaires regarding your disease and the quality of everyday life. You will have pulmonary function tests (including spirometry, lung volume measurement, diffusion function, exhaled nitric oxide measurement, induced sputum test, chest CT, 6-minute walk test, and 10 ml of blood will be collected from your arm vessels with a needle.

You may be invited to a follow-up visit for 2 years. Follow-up visits are also part of the daily diagnosis and treatment. If you are invited to attend follow-up visits, you will be required to come to the hospital for follow-up visits once a year for 2 years after the baseline visit so that we can better understand your condition.

The doctor will call you every 3 months to ask about the changes of your conditions.

This study will last for 2 years, and your treatment regimen will be decided by your doctor, and no additional investigational drug will be given.

Blood samples of 10 ml were taken 3 times throughout the study, for a total volume of approximately 30 ml.

3.3 How long will the study last?

There will be a telephone call every 3 months during the study, and you will be asked to come to hospital once a year after your baseline visit so that we can better understand your conditions.

You can withdraw from the study at any time without losing your benefits. However, we encourage you to discuss it with your doctor before you quit.

If you have a serious adverse event, or if your investigating doctor feels it inconsistent with your best interests, he/she will let you drop out. Sponsors or

regulators may also halt the study. Your withdrawal will not affect your medical care and rights.

If you withdraw from the study for some reason, you may be asked about your participation. You may have laboratory tests and physical examinations if the doctor considers it necessary.

3.4 The Information and Biological Samples

During the study, your blood and sputum samples will be collected for testing, and transported to the lab of Beijing Institute of Respiratory Diseases for storage and biomarker testing. In the future, your blood and sputum samples may be tested again, including inflammatory mediators, proteomics and genetics testing, etc. An electronic data capture (EDC) system will be used in this study. A password-protected web-based data entry platform was used to enter data of each site. The questionnaires and other relevant information about your diagnosis and treatment will be preserved in strict confidentiality to ensure that your information will not be disclosed. The information collected will only be used for purpose of this research.

4. Risks and benefits

4.1 What are the risks involved in this study?

The risks associated with attending this study may be as follows. You should discuss these risks as follows with your investigating doctor, or your regular physician if you like.

During this observational study, you may experience some, all, or none of these adverse events, risks, discomforts, inconvenience, such as discomfort of venipuncture for blood sample collection, and infection risks. We will try to avoid the infection and guide you how to prevent being infected; The induced sputum examination may cause symptoms such as breathlessness, chest tightness, dyspnea and asthma exacerbation. We will closely observe your symptoms throughout the whole process and give you corresponding treatment in a timely and active manner. 6-minute walk test may bring discomforts. Complete the test based on your strength, the doctor will accompany you to complete and assess the safety; There may be information security risks. We will do our best to protect your information from being disclosed. Some questions we ask may make you feel uncomfortable, which you can refuse to answer. You can withdraw from this study at any time.

You will be asked to come to hospital regularly and have some tests, which will take some time and may cause inconvenience.

4.2 What are the benefits?

Direct benefits: You and your physicians will learn more about your conditions and you will have better management of disease with the help of the investigating doctor.

Potential Benefits: We will pay sustained attention to the changes of your disease which may be helpful to slow the progression. Conclusions will be reached from this study that could benefit you and those who are in the same conditions.

5. Alternative treatment

There is no alternative treatment in such an observational study.

6. Use of Research Results and Confidentiality of Personal Information

With the understanding and assistance of you and other subjects, the results of the research through this project may be published in medical journals, but we will keep your research records confidential as required by law. The personal information of the research subjects will be kept strictly confidential and your personal information will not be disclosed except as required by law.If necessary, government administrative departments, hospital ethics committees and other relevant researchers can consult your data according to the regulations.

7. Study costs and compensation

7.1 Study drugs / equipment and related testing costs

The data collected in this study is partly from the necessary tests in the usual clinical visits, the costs of which will not be compensated for. Other tests that cannot be covered in usual clinical visits ,such as interleukin (IL) -4, IL-5, IL6, IL-8, IL-13, IL-33, and tumor necrosis factor (TNF)-α , will be free. The routine treatment and tests for the complications will however not be free.

7.2 Compensation

This study is an observational study, and the patients' medication and follow-up are completely in accordance with the needs of clinical routine treatment, so there will be no compensation involved.

However, compensation may be considered if the research institution fails to perform in accordance with established study protocal, causing damage to the subject due to the medical mistake. Research institutions will bear the medical expenses for subject, and take the corresponding compensation / or responsibility to compensate.

8. Rights of Subjects and Relevant Precautions

8.1 Rights

Your participation is completely voluntary. Your medical care will not be affected if you decide against to participate in this study.

If you decide to participate you must sign the consent form. You are entitled to withdraw from the study at any time without discrimination or unfair treatment, and your medical care and benefits will not be affected.

8.2 Considerations

As a subject, you need to provide a true picture of your medical history and your current physical conditions. You need to tell your investigating doctor about any discomfort, and stop some certain medicines to have some tests before your visit under the guidance of your doctor. Let your doctor know if you have recently participated in other studies or are currently participating in other studies.

9. Contact information

Your doctor will inform you promptly of any important new information that may affect your willingness to continue to participate in the study. You are entitled to know which personal data has been collected, or the conclusions of the study. You can raise any questions about this study at any time, all of which will be answered.

This study has been approved by the Ethics Committee. If you have any questions about your rights/benefits or if you want to reflect any difficulties, complaints, or concerns you may have about your participation, or if you would like to give comments and suggestions about the study, please contact the Ethics Committee of Chaoyang Hospital, No.8, Gongti South Road, Chaoyang District, Beijing. Tel: 010-852 31484, Email: cyylunli2019@163.com.

Subject Signature Page

1. I have carefully read the contents of the patient's instructions in the informed consent form of this trial/research project, and the investigating doctor has explained to me in detail and answered my relevant questions. I fully understand the purpose and process of participating in this trial/study, as well as my rights and risks. I voluntarily participate in this trial/study and agree to cooperate with the investigating doctor for treatment and follow-up in accordance with the contents of the informed consent form, and to make every effort to complete this trial/study.

Subject's signature:

(Print) _____ (Script) _____ Date_____

Or signature of an impartial witness:

(Print) _____ (Script) _____ Date_____

Or guardian's signature (if necessary):

(Print) _____ Immediate relationship to subject: _____

(Handwriting) _____ Date _____

2. I or my investigator have fully explained and explained to the subject the objective, background, process, risks and benefits of the trial/study and have satisfactorily answered all relevant questions of the subject.

Signature of investigator or investigator's designated advising physician:

(Print) _____ (Script) _____ Date _____

Both the subject and the investigator were required to sign 2 copies of the same informed consent form, and each party kept one copy.