Informed Consent Form

A Prospective Clinical Follow-up Study of Drug Treatment in Patients with Graves' Disease

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A Prospective Clinical Follow-up Study of Drug Treatment in Patients with Graves' Disease

Dear Mr/Ms xxxx,

We invite you to participate in the study entitled "Prospective Clinical Follow-up Study of Drug Treatment in Patients with Graves' Disease." This study will be conducted in the First Affiliated Hospital of China Medical University. The study has been reviewed by the Medical Science Research Ethics Committee of the First Affiliated Hospital of China Medical University. Please read the following carefully before deciding whether to participate in the study to help you understand the study. If you have any questions, please ask them in time and your doctor will answer them for you. If you like, you can also discuss it with your relatives and friends to help you make a decision. The following is an introduction to the project study:

I. Background

With the increase of social competition pressure and the acceleration of life rhythm, the prevalence of hyperthyroidism increases year by year. In 2016, the epidemiological survey results of thyroid diseases among 15000 people in 10 cities in China showed that the prevalence rate of hyperthyroidism was as high as 1.6%, of which Graves' disease (GD) accounted for about 92%. GD has become one of the common epidemic diseases today.

There are three conventional treatments for GD: oral antithyroid drugs (ATD), radioactive iodine (RAI), and subtotal thyroidectomy. RAI and subtotal thyroidectomy are invasive treatments that may lead to hypothyroidism. ATD is the preferred treatment for GD.

II. Purpose of research

The aim of this study was to analyze the remission rate, recurrence rate and risk factors for recurrence of Graves' disease by prospective follow-up study of newly diagnosed and relapsed Graves' disease patients in the Endocrinology Clinic of the First Affiliated Hospital of China

Medical University. To obtain and analyze the prevalence of side effects and risk factors of drug therapy in patients with Graves' disease. To evaluate the sensitivity and specificity of TRAb in the diagnosis of Graves' disease and its role in predicting recurrence. To accumulate experience in the treatment of Graves' disease in China and provide domestic experience for the formulation of hyperthyroidism guidelines in China.

III. Research contents

1. Patient inclusion criteria

①Newly diagnosed GD and GD relapses.

②Patients with active infiltrative exophthalmos in GD were excluded.

③Patients with other autoimmune diseases affecting thyroid function were excluded.

④Excluding patients with combined malignancies and other serious diseases.

⑤Patients who signed the informed consent form.

2. Stages of research

According to the guideline recommendation, the patient will be followed up every month before thyroid function is normal, and 2-3 months after thyroid function is normal. Blood samples will be collected at follow-up, thyroid function, liver function, TRAB and blood routine tests will be performed, and medication guidance will be provided.

IV. What aspects of your cooperation are needed in the study

Patients participating in this study need to cooperate with follow-up. Before normal thyroid function, they need regular follow-up every month, and follow-up 2-3 months after normal thyroid function. Routine diagnosis and treatment were carried out during follow-up, thyroid function, blood routine and liver function were monitored, and TRAB test was performed every 3 months. We will retain the patient's blood samples for subsequent studies.

V. Possible benefits of participating in the study

1. Benefits of the study to the subjects themselves

If you agree to participate in this study, you will receive free advice on diet and medication related to this disease from your doctor on WeChat.

To obtain follow-up during GD treatment and after discontinuation, reduce the risk of GD recurrence and improve the cure rate.

2. Benefits of research for social groups

Through prospective follow-up studies of GD patients, the clinical data we have accumulated will provide clinicians with more experience in diagnosis and treatment, reduce the recurrence rate of GD patients and improve the cure rate.

VI. Economic problems

1. The examination items of subjects are routine examination items for diagnosis and treatment, including the cost of TRAB test once every 3 months. The examination items of this study are not exempted from fees.
2. Follow-up subsidies and compensation will not be given to the subjects participating in this trial.

VII. Voluntary participation/withdrawal

Participation in this study is voluntary. You can refuse to participate or withdraw from the study at any time. You will not be discriminated against, treated unfairly or retaliated, and your medical treatment and rights will not be affected in any way.

VIII. The confidentiality of personal information

Your samples will be used for the above mentioned research projects. We will keep your test results strictly confidential. After the project is completed, the remaining samples will be stored in the biological sample bank of the research group for other related scientific research. During the research process, only the investigators and authorized personnel of the investigators can see your information. The aggregate data from this study may be published in medical journals and/or presented to authoritative academic institutions worldwide, but will not involve your identity and personal privacy.

IX. Contact information

You can ask any questions about this study at any time. You can contact your doctor at: Teng Xiaochun Tel: 024-83283135. If you have any complaints about participating in the study, please contact the Ethics Committee at 024-83282837.

Declaration of consent

1. I have carefully read the above description of this study and have had the opportunity to discuss and ask questions about it with doctors. All my questions have been answered satisfactorily.
2. I understand that participation in the study is voluntary, I confirm that I have had sufficient time to consider it, and understand that:

1) I am aware of the potential risks of participating in the trial and the treatment of those risks once they occur;

2) I am aware of alternative treatment options relevant to this trial;

3) I can ask my doctor for more information at any time;

4) I can withdraw from the study at any time without discrimination and retaliation, and my medical treatment and rights will not be affected;

Finally, I decided to agree to participate in this study and am willing to cooperate with the doctor to complete this study as required by the study protocol.

Subject Signature: Date:

I have fully explained and explained the purpose of this study, the operation process and the possible risks and benefits of the subject's participation in this project, and answered all the relevant questions of the subject satisfactorily.

Investigator Signature: Date: