Informed consent form for the evaluation of the clinical efficacy of different doses of LT4 in the treatment of pregnant women with normal-high TSH and TPOAb positivity in the first half of pregnancy

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Dear Sir/Madam:

We would like to invite you to participate in a study on "Evaluation of the clinical efficacy of different doses of LT4 in the treatment of pregnant women with normal-high TSH and TPOAb positive in the first half of pregnancy". This study has been reviewed and approved by the Medical Ethics Committee of the Third Affiliated Hospital of Zhengzhou University. This informed consent form will introduce you to the purpose, steps, benefits, risks, inconveniences and your rights and interests of the study. Please read it carefully and make a careful decision whether to participate in the study. When the researcher explains and discusses the informed consent form with you, you can ask questions at any time and ask him/her to explain to you that you don't understand. You can make a decision after discussing with your family, friends and your attending physician.

The project leader of this study is Professor Xu Yajuan, and the project and research funds come from provincial grants and self-raised funds.

1. Why is this study conducted?

Pregnant women with normal-high TSH and positive TPOAb are closely related to adverse pregnancy outcomes such as miscarriage, premature birth, low birth weight, fetal distress, and intellectual disability in infants and young children. Studies have shown that taking levothyroxine (LT4) can reverse the harmful effects of TPOAb levels, improve patients' thyroid function, and reduce the incidence of adverse pregnancy outcomes such as gestational diabetes, premature rupture of membranes, miscarriage, premature birth, and macrosomia. High doses of LT4 may cause adverse reactions such as palpitations, insomnia, sweating, and nausea.

Therefore, this study explores the differences in clinical efficacy of different doses of LT4 in the treatment of pregnant women with normal-high TSH and positive TPOAb in the first half of pregnancy.

2. What does this study include?

Personal information of pregnant women included in the study is collected, mainly including age, height, weight, pregnancy and delivery history, etc., and thyroid function level is collected through the electronic medical record system. Feces of pregnant women included in the study are collected for 16S rRNA genomic sequencing, and 5ml of peripheral blood is collected for determination of inflammatory immune indicators, etc. Various serological indicators and pregnancy outcome information of pregnant women included in the study are counted.

3. How long will this study last? 1 year

4. What are the risks of participating in this study?

The information collected by this study is obtained from previous diagnosis and treatment, and the drug levothyroxine in this study has no contraindications during pregnancy. Patients do not need additional diagnosis and treatment activities, and their health and rights will not be damaged. The stool specimens collected in this study are normal excrement, and the peripheral blood content collected is low, which will not have an adverse effect on the subjects. All personal information and data results of the pregnant women in the group are

strictly confidential and anonymous, and will be destroyed immediately after the study is completed.

5. What are the benefits of participating in this study?

Your participation will help us study the therapeutic effect of levothyroxine on pregnant women with normal-high TSH and positive TPOAb and its impact on maternal-child outcomes.

6. Do I have to participate in and complete this study?

Your participation in this study is completely voluntary. If you do not want to, you can refuse to participate. This will not have any negative impact on your current or future medical treatment, and the doctor will treat you according to routine medical treatment. Even after you agree to participate, you can change your mind at any time and tell the researcher to withdraw from the study. Your withdrawal will not affect your access to normal medical services. In principle, after you withdraw, the researcher will strictly preserve the relevant information obtained from you until it is finally destroyed, and will not continue to use or disclose this information during this period. During the study, if there is any information that may affect your decision whether to continue to participate in the study, we will inform you in a timely manner.

7. What are the costs and compensation for participating in the study?

The genomics and flow cytometry tests involved in this study are free of charge, and all subjects can be given priority to visit the obstetrics outpatient clinic for perinatal care and hospital delivery if conditions permit.

8. Will the subjects be paid for participating in this study? No.

9. What happens if research-related injuries occur?

The medical information collected by this study is obtained through routine perinatal care. When collecting peripheral blood from pregnant women, it is often done simultaneously with other similar blood tests. Usually, no additional blood is required, and the amount of blood collected is small, which causes minimal harm to the research subjects. The remaining samples are collected non-invasively, and the overall risk is low. All personal information and data results of the enrolled pregnant women are strictly confidential and anonymous, and will be destroyed immediately after the study is completed.

10. Will my information be kept confidential?

If you decide to participate in this study, your participation in the study and your personal information in the study will be kept confidential. The specimens collected from you will be identified with the research code rather than your name. No information that can identify you will be disclosed to members outside the research team without your permission. All research members and research stakeholders will keep your identity confidential as required. Your file will be kept in a locked filing cabinet and only available to researchers. If necessary, members of the government management department or ethics committee can access your personal information at the research unit as required. When the results of this study are published, no information about your identity will be disclosed.

If you have any questions related to your own rights and interests, you can contact the Medical Ethics Committee of the Third Affiliated Hospital of Zhengzhou University.

Signature of the subject/subject guardian: Date:

Signature of the researcher: Date: