Observational study of the correlation between peripheral Treg cell senescence and serum total cholesterol level

Version: 1.0

Date: December 1st, 2022

Ethics Committee

Tianjin Medical University General hospital

Information Sheet of Informed Consent Form

Dear potential research participants,

We sincerely invite you to participate in a study titled ***Observational cohort study of the correlation between peripheral Treg cell senescence and serum total cholesterol level***. This research is supported by **the Department of Geriatrics, Tianjin Medical University**. The principal investigator is **Prof. Ping Lei**, and the project executor is **Dr. Xintong Ge**.

The ethics committee of Tianjin Medical University General Hospital has reviewed the research plan of this study, and agreed to con**d**uct the clinical research program (Grant No. **IRB2022-YX-244-01**, Approved starts on: **12/01/2022**, Approval expires on: **03/31/2023**). The study has been registered at the global clinical research authority database, **ClinicalTrials.gov (Identifier: NCT)**. The research program is funded by **the Natural Science Foundation of China (Grant No. 82071394, 82072166)**.

Please read the following text carefully as much as possible before deciding whether participate in this study. It can help you understand the purpose, content, procedures and duration of the study, and the possible benefits, risks and discomforts of being a participant. If you prefer, you can also discuss with your family and friends, or ask your doctor for explanations to help you make a decision. In addition, taking part in this study is entirely voluntary. You can refuse to participate, which will not affect your relationship with the doctor and the investigator. In addition, you will not be charged any additional fee.

1. Research Background and Objectives

Hypercholesterolemia is a risk factor for the occurrence and development of atherosclerosis. Recent animal studies have found that increased serum cholesterol level is associated with peripheral Treg cell senescence, but clinical evidence is still lacking. The purpose of this study is to analyze the correlation between human peripheral Treg cell senescence and serum total cholesterol level using clinical blood samples, thus laying a foundation for the establishment of novel therapeutic strategies for atherosclerosis based on the regulation of Treg cell senescence.

2. Estimated Number of Subjects

A total of 200 subjects were randomly selected from the population receiving physical examination in the Cadre Physical examination Center of Tianjin Medical University General Hospital from January 2023 to March 2023.

3. Inclusion and Exclusion Criteria

3.1 Athletes and Patients with TBI

Inclusion Criteria:

1) Age ≥ 30 and ≤ 60 years old with independent behavior ability.

2) The participants need to fully understand the purpose and content of the study, and voluntarily participate in the study and sign the informed consent.

Exclusion Criteria:

1) Pregnant or lactating women.

2) Acute and severe diseases in the last 3 months, including but not limited to, acute myocardial infarction, acute cerebral infarction, cerebral hemorrhage, circulatory failure, respiratory failure (internal diseases), trauma requiring hospitalization, or undergoes surgery under general anesthesia (surgical diseases).

3) History of severe diseases, including but not limited to, tumors, serious hematological diseases, serious cardiopulmonary diseases (interventional therapy for coronary artery disease, atrial fibrillation, chronic obstructive pulmonary disease, etc.), renal failure, liver failure, old stroke with serious sequelae.

4) Have participated in clinical trials in the past 3 months.

5) The investigator considers that not appropriate for inclusion.

4. Study Procedures

4.1 Before you enroll in the study, the doctor will record your past medical history and medication (especially hypolipidemic drugs) in the past 3 months.

If you are a qualified subject, you could voluntarily participate in the study, and sign the informed consent.

If you do not meet the inclusion criteria, we will suspend your participation in this study.

4.2 If you agree to participate in the study, an additional 6 ml of venous blood will be drawn during your routine blood tests for examinations of Treg cell senescence. The collected blood samples will only be used in this study.

5. Benefits

All participants will be given a carotid artery B-ultrasound examination (valued at ¥ 300) at the Cadre Physical examination Center of Tianjin Medical University General Hospital

6. Risks, Discomforts and Inconveniences

1) The doctor will collect your past medical history during the research, which will take 5-10 minutes, and may lead to some inconvenience for you.

2) When you receive the routine blood tests, an additional 6 ml of venous blood will be drawn for follow-up study. It may cause you pain, but will not affect your health.

7. Financial Information

You will not be charged for participating in this study.

8. Privacy

Your research records will be kept by Tianjin Medical University General Hospital. The investigator and the clinical trial management agency will be permitted to assess your records. Any public report on the results of this study will not reveal your personal information. We will make every reasonable effort to protect the privacy of your personal research records.

According to medical research ethics, the research data will be available for public inquiry and sharing. The query and sharing will be limited to web-based electronic data, ensuring that no personal privacy information will be disclosed.

9. Voluntary Participation and Withdrawal

Participating in this study is completely voluntary. You may refuse to take part in this research, or stop participation at any time that you wish without losing any of your rights. For your best interests, the doctor and the investigator may stop your participation at any time during the study.

10. What need to do now?

Thanks for reading the materials. Before making a decision on whether to take part in this study, please ask the doctor or the investigator about the research as much as possible. If you decide to participate, please tell your research coordinator, he will arrange everything for your participation.

Please keep this form properly.

11. Sharing the Results

Your physical examination report will be mailed to your home within 1 month after the examination. In addition, the results of this study will be published and shared through academic papers, professional academic conferences, internet, Wechat, etc., so that the practitioners in the medical field can learn.

12. Who can I contact about this study?

Project executor: Dr. Xintong Ge; E-mail: gexintongbob@163.com; Telephone: 022-60364359

Research Coordinator: Dr. Zhenyu Yin; E-mail: yzyexosome@163.com; Telephone: 022-60362237

Program Assignment No. IRB2022-YX-244-01

Certificate of Informed Consent Form

Study Title: Observational study of the correlation between peripheral Treg cell senescence and serum total cholesterol level

Name of Organization: Tianjin Medical University General Hospital

Consent Statement:

I have read the above introduction to this study, and have the opportunity to discuss it with **Dr. Xintong Ge**, the project executor of the research program. All the questions I asked have been satisfactorily answered.

I know that participating in this study is completely voluntary. I understand the risks and benefits that may arise from taking part in this study. I confirm that I have enough time to consider, and realize that:

- I can ask the doctor and the investigator for more information about the study at any time.
- I can withdraw from the study at any time without discrimination or retaliation, and my rights will not suffer any loss.
- If I have more questions or concerns about this research, I can contact with **Dr. Xintong Ge**.

I agree that the investigator and the ethics committee could review my research materials.

I will receive a copy of this form with my signature and the date.

Finally, I decide to agree to participate in this study, and promise to do my best to follow the instructions from the doctor and the investigator.

Name of participant: _____ Telephone: _____ Date: _____

I confirm that the details of this study have been stated to the participant, including his/her power, potential benefits and risks. The participant has been given opportunities to put questions about the study, and all the questions have been answered accurately. I confirm that the participant was not coerced into giving consent, and a copy of this form has been provided to him/her.

Name of Doctor: _____ Date: _____