Bacteria in Atherosclerotic Plaques and Adverse Events

Informed Consent Form

ClinicalTrials.gov ID：NCT06935279

Department of Neurosurgery

Tangdu Hospital

Date: 28 February 2024

Bacteria in Atherosclerotic Plaques and Adverse Events

Informed Consent Form

Dear Participant,

We are initiating a clinical research project titled "**Bacteria in Atherosclerotic Plaques and Adverse Events**". As you are scheduled for carotid endarterectomy and your specific circumstances meet the inclusion criteria for this study, we would like to invite you to participate.

This informed consent form outlines the study's purpose, procedures, potential benefits, risks, inconveniences, and your rights. Please read it carefully before making an informed decision about participation. During the discussion of this form with the investigator, feel free to ask questions and request clarification on any points you do not understand. You may also consult with family, friends, or your treating physician before deciding.

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

The principal investigator for this study is Associate Professor Liu Bei from the Department of Neurosurgery at Tangdu Hospital, Air Force Medical University.

1. Why conduct this research?

Atherosclerosis is not merely a disease of lipid deposition, and bacteria within plaques are not harmless bystanders. Instead, they actively participate in and drive disease progression through multiple mechanisms. Bacteria (especially intracellular bacteria) serve as significant destabilizing factors that promote inflammation and plaque formation. Their detrimental effects span the entire process of plaque formation, progression, and rupture, with core hazards summarized as follows: ① Triggering and persistently amplifying local inflammatory responses within plaques; ② Compromising the structural stability of plaques; ③ Inducing thrombus formation within plaques; ④ Contributing to the synergistic harm of systemic inflammation and metabolic disorders.

One of the core pathological foundations of stroke (particularly ischemic stroke, accounting for approximately 70% of cases) is the formation of atherosclerotic plaques in locations such as the carotid arteries and intracranial arteries, leading to vascular stenosis, plaque rupture, or thrombus detachment. Bacteria, especially intracellular bacteria, can directly or indirectly exacerbate the risk and severity of stroke. The primary mechanisms include: Accelerating arterial narrowing, leading to insufficient cerebral perfusion; 2. Inducing vulnerable plaque rupture, causing acute thrombotic stroke; 3. Exacerbating brain tissue damage following stroke. Therefore, the presence of intracellular bacteria poses a serious threat to human health.

The discovery of intracellular bacteria has prompted researchers to explore their role in disease treatment, driving investigations into intracellular microbiology to uncover novel therapeutic approaches. While the impact of arterial plaque microbiota on plaque treatment remains inconclusive, intracellular bacteria therapy currently focuses on cancer treatment. In clinical cancer management, antibiotics or antiviral drugs are currently used only against known carcinogenic microorganisms such as Helicobacter pylori, hepatitis viruses, and human papillomavirus. The use of antibiotics remains controversial, particularly systemic administration which may compromise immune function in cancer patients and disrupt gut microbiota balance, necessitating cautious application. Intracellular bacteria evade host immune surveillance by residing within host cells. The membrane barrier function of host cells prevents antimicrobial drugs from penetrating intracellularly to eliminate bacteria, making intracellular bacterial infections a significant therapeutic challenge. Therefore, conducting research on the distribution of intracellular bacteria in arterial plaques and analyzing related risk factors to identify plaque bacterial characteristics for targeted treatment holds significant importance for preventing cerebral infarction due to carotid artery stenosis.

This project aims to establish a registry center for patients experiencing adverse events following carotid artery stenosis surgery. Derivative analyses will be performed on patients who underwent relevant plaque testing within a specific period post-surgery to derive corresponding expected conclusions.

All patients participating in this study undergo comprehensive standardized evaluations by a multidisciplinary team (including neurology, neurosurgery, hematology, endocrinology, and other practitioners). Assessments cover neurological, neuropsychological, and psychiatric examinations, endocrine disorders, and hematological indicators.

Selected patients receive conventional surgical treatment and follow-up visits as recommended by physicians, with corresponding clinical practice data accurately recorded. Data generated during clinical visits will be recorded, including:

- Inpatient examinations and assessments
- Preoperative evaluations
- Preoperative care
- Operating room care
- Anesthesia management
- Intraoperative procedures
- Postoperative medical management
- Postoperative nursing care
- Follow-up information

2. Who will be invited to participate in this study?

Citizens aged 18 to 90 years who meet the inclusion and exclusion criteria for this study.

3. How many participants will be enrolled?

This study will be conducted primarily at the Department of Neurosurgery, Tangdu Hospital, Air Force Medical University, with an anticipated enrollment of 200 patients.

4. How will the study be conducted?

Patients enrolled in this study will undergo examinations and scheduled treatments during hospitalization based on clinical practice. Please inform us of any changes during your treatment.

If you consent to participate, your treating physician (who is also the study investigator) will conduct an admission assessment to understand your baseline condition. Preoperative discussions will cover your medical history, lifestyle, medication use, and questionnaire evaluations. The study will also document physical examination findings, laboratory results, and imaging data obtained during routine clinical visits. Additionally, the study will record your preoperative preparation, intraoperative management, and the occurrence of adverse events/serious adverse events.

5. How long will this study last?

This study involves the accurate recording of your clinical data during your inpatient surgical period. The study period spans from hospital admission to 90 days post-surgery.

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

This is an observational, non-interventional registry study, so there are no disadvantages to you. Your treatment during and after the study will proceed as usual and will not be affected by your participation.

This project does not involve any investigational drugs, invasive procedures, or interventional treatments.

If you agree to participate, all your information will be kept strictly confidential. Only you and the relevant research team will have access to your written and electronic medical records to verify the accuracy of the collected data. Study results may be presented at medical conferences and published in scientific journals domestically and internationally; however, no personally identifiable information will be used. To ensure the accuracy of your medical information and to complete follow-up visits and quality-of-life surveys when necessary, your physician and the study researchers may contact you. We kindly request you to provide your contact information on this informed consent form. This information will be retained by the hospital and research institution and will only be accessible to your physician and authorized researchers responsible for the quality-of-life surveys. No other unrelated personnel or collaborating institutions associated with this project will have access to this information.

All examination information regarding your condition and research findings will be provided to you upon request.

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

As a long-term, observational, non-randomized registry study, this research aims to identify intracellular bacterial species through carotid plaque analysis. Combined with clinical data, it analyzes associated risk factors to distinguish bacterial species linked to adverse outcomes (cerebral infarction, carotid restenosis, mortality). This approach enhances the clinical efficacy of carotid stenosis treatment, ultimately preventing cerebral infarction and conserving healthcare resources—demonstrating practical clinical value.

Additionally, you will receive direct and comprehensive medical monitoring. Your physician will gain detailed insights into your disease progression and associated symptoms. Treatment and care plans will be tailored to your actual physical condition, with close attention to your health status.

8. Is participation in and completion of this study mandatory?

You have the full right to decide whether to participate in this study. If you choose to participate, you may withdraw at any time during the study without needing to provide a reason. Your decision to withdraw or decline participation will not affect the standard of care you receive from the hospital.

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

This is an observational, non-interventional study that documents actual clinical care provided. The study will not cover costs associated with routine clinical care (including examination fees, transportation costs, lost wages, etc.).

10. Will participants receive compensation?

As an observational, non-interventional study requiring objective clinical data collection, no compensation will be provided to patients participating in this research.

11. How are study-related injuries handled?

This is an observational, non-interventional study. Any adverse medical events occurring to patients or clinical research subjects during the study will be managed according to standard clinical protocols.

12. Will my information be kept confidential?

If you agree to participate in this study, all information about you will be kept confidential. Furthermore, the information collected and reported by the researchers will not include your name.

13. Who should I contact if I have questions or concerns?

After reviewing this information and discussing it with your doctor, if you have further questions or concerns, please contact:

Principal Investigator (Researcher):

Phone Number:

Hospital Name: Address:

For questions regarding your rights, contact the Medical Ethics Committee at:

Informed Consent Form (Signature Page)

Researcher's Declaration

I have informed the subject about the background, purpose, procedures, risks, and potential benefits of the study titled "**Bacteria in Atherosclerotic Plaques and Adverse Events**". I have provided sufficient time for the subject to read the informed consent form and discuss it with others, and I have answered all questions regarding the study. I have informed the subject that they may contact Associate Professor Liu Bei at any time regarding research-related questions and may contact their physician at any time regarding issues related to their rights/interests, and have provided accurate contact information. I have informed the subject that they may withdraw from this study at any time without providing a reason. I have informed the subject that they will receive a copy of this informed consent form bearing both my signature and theirs.

Researcher Signature for Informed Consent (Cursive) Date

Researcher Signature for Informed Consent (Printed) Date

Subject Declaration

I have been informed about the background, purpose, procedures, risks, and benefits of the study titled "**Bacteria in Atherosclerotic Plaques and Adverse Events**". I had sufficient time and opportunity to ask questions, and I am satisfied with the answers provided. I have also been informed of whom to contact if I have questions, wish to report difficulties or concerns, have suggestions for the study, seek further information, or wish to assist with the research. I have read this informed consent form and agree to participate in this study. I understand that I may withdraw from this study at any time during its duration without needing to provide a reason. I have been informed that I will receive a copy of this informed consent form bearing my signature and that of the researcher.

Participant Signature: Date

Contact Number: (Home) (Mobile)

When the subject lacks full or limited legal capacity, their legal representative must sign on their behalf.

Legal Representative Signature: Date:

Contact Number: (Home) (Mobile)

Reason for Representation: Relationship: