**Informed Consent**

**Title of the study：**

Effect of systemic inflammatory response attenuating cardiopulmonary bypass strategy reduces new ischemic/embolic lesions after acute type A aortic dissection surgery: the sirA-CPB randomized clinical trial.

**Centres where the study will be performed：**

Department of Cardiothoracic Surgery, Xiangya Hospital, Central South University

**Protocol Version:**

2.0 (2026-04-01)

**Informed Consent Version:**

2.0 (2026-06-08)

**Local principal investigator:**

Lian Duan, Xiangya Hospital, Central South University

**Informed Consent**

Dear Sir/Madam

We are conducting a single center randomized controlled trial on the superiority of the sirA-CPB strategy in reducing new ischemic/embolic lesions after acute type A aortic dissection surgery compared to traditional CPB. This study has been reviewed and approved by the Clinical Ethics Committee of Xiangya Hospital, Central South University(No.202606087).

Your situation meets the inclusion criteria for this study, therefore, we sincerely invite you to participate in this research. Your participation is completely voluntary, and you can choose to participate or not. This informed consent form will introduce you to the background, purpose, process, methods, risks, and potential benefits of the study, as well as describe how your medical information will be utilized and who will access it. Please read carefully and make a cautious decision on whether to participate. When the research doctor or relevant researcher explains and discusses the informed consent form to you, you can ask questions at any time and ask him/her to explain to you what you don't understand. You can also discuss with family, friends, and your research doctor before making a decision. This informed consent form is in duplicate, and you and your research doctor will each receive one copy.

**1. Research institutions, specialties, and researcher qualifications**

Xiangya Hospital,Central South University is a tertiary Grade A hospital that integrates clinical practice, scientific research, and teaching. It is one of the clinical trial institutions certified and filed by the National Medical Products Administration. The cardiothoracic surgery major has obtained the national registration permit and meets the basic conditions for conducting clinical trials. The main researcher of this study, Duan Lian; Chief physician of Cardiovascular Surgery at Xiangya Hospital; who led multiple clinical trials at the national and provincial levels in the past.

**2. Background**

Type A acute aortic dissection (TAAAD) is a life-threatening condition, which often requires emergency surgery to prevent major bleeding caused by rupture, while insufficient attention paid to its embolic morbiditie. Previous literature has defined multiple types of morbidities based on separate organs or systems, such as stroke, myocardial infarction, renal failure, pulmonary embolism, etc. We wonder almost thrombosis of these morbidities, few studies have viewed them as a whole imbalance in coagulation state, while hemorrhage in surgical and non-surgical areas is usually classified as the same category of bleeding. Recent studies showed that TAAAD patients who survived 3 months after surgery, the 2-year and 10-year observed mortality were >25%, >40%, respectively. These data are much higher than the 9.8-10.6% hospitalization mortality. Although postoperative anticoagulation is routine in clinic, consensus emphasize the monitoring connective tissue disease progression, long-term lifestyle habits and medication, yet a perioperative one is difficult to find. TAAAD as a typical disease, which is necessary to be observed the detailed situation of ischemic/thromboembolic events (ITEs), in order to determining perioperative risk factors, whether they can be regulated, preparing for standardized perioperative ITEs prevention protocol in the future.

The innovation of this study lies in its antithrombotic approach from the perspective of reducing inflammation, without interfering normal coagulation pathways, so adverse reactions such as excessive bleeding caused by previous antithrombotic drugs or embolism caused by inadequate antithrombotic standards are eliminated. The sirA-CPB (systemic inflammatory response attenuating cardiopulmonary bypass) strategy of in this study may reduce contact activation, complement activation, cytokine secretion, etc., which belongs to the intervention of pre coagulation mechanisms or pathways. So far, our research group has not found any relevant clinical studies published.

**3. Aim of the project.**

The body enters an acute systemic inflammatory state after major cardiac surgeries such as acute type A aortic dissection, which can promote coagulation overactivation and thrombus formation, leading to various ischemic/thromboembolic complications. Routinely administering early postoperative anticoagulants affects the normal coagulation pathway and leads to excessive bleeding. This study aims to reduce postoperative ischemic/thromboembolic lesions through non-pharmaceutical sirA-CPB strategy with a novel anti-inflammatory approach without affecting the coagulation process.

**4. Research process**

Prospective, randomized, single-blind and controlled study. Patients who require TAAAD open surgery with CPB with a planned duration of more than 120 minutes will be candidates to participate in the study. Those who meet the inclusion criteria, after providing signed informed consent, will be randomized using a sequential randomization program to one of the two treatment arms:

• sir-A CPB: Maintain mean artery pressure (MAP) 65-100 mmHg during the whole CPB period, reinfusion shed blood after adsorption, limiting air-blood contact, pulsatile mode and no ultrafiltration unless necessary.

• Standard-CPB: conventional CPB without intervention.

If you meet the inclusion criteria, you will sign this informed consent form after signing the surgical consent form. Our sirA strategy will be implemented during the surgery, using routine supplies for CPB. Whether you belong to the control or the intervention group, you will use these consumables. There will be no other interventions before or after surgery, and the collected indicators will be the part of routine tests required for perioperative hospitalization. We have dedicated personnel for data collection and follow-up, which will not increase your financial burden or disclose your personal information. For the control group, we will use the traditional CPB strategy; The intervention group will adopt a sirA-CPB strategy, and may also switch to traditional CPB strategy if requested by the chief surgeon or in emergency situations during the operation.

The inclusion criteria for this study are patients aged ≥ 18 years who are planning to undergo open TAAAD surgery. If you match the criteria, we will arrange to introduce you to this study.

If you have not signed the informed consent; Currently participating in other clinical trials; Have communication impairments in thinking, language, or hearing; History of mental illness, coagulation dysfunction or hematological disorders; Severe liver or kidney dysfunction; refuse

blood transfusions (Jehovah Witness); Fever exceeding 38 ℃ or combined with systemic infection; We will not include you in this study.

**5. Subject cooperation**

We will telephone you at 1 month, 3 months, 6 months, 12 months, 24 months, and 36 months after discharge. Please reply to any questions related to treatment and rehabilitation, and agree to our inquiry of your follow-up information.

**6. Benefits of participating in this study**

Possible benefits: Reduce the incidence of systemic inflammation or infection after surgery, potentially reduce deep vein thrombosis, central nervous system dysfunction, cardiac, pulmonary, or renal complications, decrease transfusions, and reduce transfusion related costs. Meanwhile, the information obtained through your participation will contribute to medical progress and benefit patients with similar conditions in the future.

Of course, you may also not benefit: this treatment may not reduce the patient's inflammatory response or transfusion, or postoperative complications related to the nervous system, heart, lungs, or kidneys.

**7. Risks and inconveniences associated with participating in this research**

The intervention in this study will be implemented intraoperatively, so the potential risks associated with this study include surgery related risks and research related risks. Research related risks include hemolysis caused by excessive negative pressure destruct red blood cells, empty intake of air from the reservoir, and vasopressors increasing. These risks are controllable and can be immediately addressed. Because according to our preliminary trial results, this treatment has been used normally in our department for six months without any risks or adverse events, and we have complete anti risk measures, such as controlling negative pressure and flow within a certain safe range. If it exceeds this range, it will automatically pause; There is liquid level monitoring to automatically stop the pump and prevent air intake.

Surgery related risks include anesthesia accidents, surgical site bleeding, postoperative nausea and vomiting, sleep disorders, incision pain, pleural effusion, severe ventricular arrhythmias, myocardial infarction, coronary or aortic bleeding, pulmonary infarction, renal failure, respiratory failure, liver failure, stroke, abnormal test values, etc. These adverse events are not related to this study and the researchers do not assume responsibility, but they will be recorded truthfully and treated and handled according to clinical routine.

**8. Alternative treatments outside of this study**

None.

**9. Free treatments and other related subsidies, as well as free medication and examinations during research period**

The treatment and examination items used in this study are currently commonly used in clinical practice, and the test results collected in this study are also routine clinical items during the diagnosis and treatment process. There is no need to increase the patient's financial burden, nor provide financial assistance.

**10. Treatment and economic compensation for research related injuries**

During the research period, if you feel any discomfort, please communicate with your research doctor and researchers in a timely manner to ensure that you receive necessary care and treatment.

**11. Rights of research participants**

Voluntary participation: Your participation is entirely voluntary, and the research team will not force or induce you to join in any way.

Withdraw at any time: You may withdraw at any stage of the study without reason and without any liability, and your medical treatment and legal rights will not be affected as a result.

Autonomous decision: You can choose to agree or refuse to participate in the study, or decide whether to continue participating after learning new information.

Right to Sign Again: If there are substantial changes to the research content (such as protocol adjustments, risk updates, etc.), the research team will explain to you again, and you have the right to decide whether to sign a new version of the informed consent form.

You have the right to learn about the progress of research and access research results related to your own health through researchers. Please note that any information collected before you withdraw your informed consent will be saved and used to complete this study.

**12. New information acquisition in clinical research**

If we obtain new information that may affect your decision to continue participating in the study, the research team will promptly inform you through the contact information you provided. You have the right to independently decide whether to continue participating in the study after learning new information. You may be required to sign a new informed consent form to record the updated information you have received, but this decision will not affect the medical treatment you should have received.

**13. Protection of privacy and personal information**

13.1 Your personal information (such as name, medical records, examination results, etc., written according to the actual collection of personal information for the project) will be strictly kept confidential, used only for research purposes, and not disclosed to unrelated third parties. Your real identity information will be replaced by a "research participant authentication code".

13.2 When sponsers, researchers, ethics committees, and regulatory authorities need to access your information for review, they will follow the principle of confidentiality to ensure that the information is not leaked.

13.3 All informed consent documents should be archived together with the original research data, with a retention period of no less than five years after the end of the study, to ensure that the data is properly stored within the prescribed period. Electronic documents are only authorized for researchers to access through passwords, while paper documents will be stored in a locked file cabinet to prevent unauthorized access.

**14. Contact information**

If participants have any questions, discomfort or injury during the research process, please consult your research doctor: Duan Lian, phone: 13549652849; If you have any questions regarding your rights during the

trial, you can call the Ethics Committee of Xiangya Hospital at 073184327919. The information registered for this clinical study will be published on the clinicaltrials.gov website.

**15. Registration and information disclosure**

According to relevant national regulations, the information of this study will be recorded in the National Medical Research Registration and Filing Information System (China, official Chinese name: 国家医学研究备案系统) https://www.medicalresearch.org.cn/login, filing number: _____. You can log in to this website to learn about research related information.

**Consent section**

1. I have carefully read this informed consent and have had the opportunity to ask questions. The researchers have provided me with detailed explanations and answered my relevant questions. I understand that participating in this study is voluntary, and I can withdraw at any time without giving a reason, and my medical and legal rights are not affected. I allow the sponsor, researchers, ethics committee, and health supervision department to view my medical records, and I understand that the sponsor will take all reasonable measures to protect my privacy. I agree to participate in this study.

Subject signature： Date：

Phone：

Signature of the subject's guardian (if applicable)：

Phone：

Relationship with the subject：

Date：

2. I or my researchers have fully explained to the subject the purpose, operation process, potential risks and benefits of participating in this clinical trial, and satisfactorily answered all relevant questions from the subject. I have fully recorded the communication time, method, key points of content, and answers to questions from the subjects regarding this informed consent.

PI or researcher designated by PI(who informs the subjects):

PI signiture(print script)： Phone：

PI signiture(handwritten) ： Date：

Researcher designated by PI(print script)： Phone：

Researcher designated by PI(handwritten)： Date：