

Informed Consent Form

Official Title of the study: Establishment of Systemic Prevention and Management for Perioperative Hypothermia and Its Effect on Patients Outcome—a Prospective Multiple Centers Randomized Controlled Study

Identifiers: [NCT ID not yet assigned]

Unique Protocol ID: *Hypothermia2018*

Brief Title: Systemic Prevention and Management for Perioperative Hypothermia and Its Effect on Patients Outcome

Latest edition: September 20th 2018

Dear Sir/Madam, you are invited to participate in this study because you may be eligible for the inclusion of the clinical study of Systemic Prevention and Management for perioperative hypothermia. Your research doctor or researcher will fully explain the contents of the informed consent form to you. Please carefully read the informed consent form and decide whether to participate in the study. If you are participating in another study, please let your research doctor or researcher know.

1. Why we are conducting this research?

This study was designed to investigate the Establishment of Systemic Prevention and Management for perioperative hypothermia and its effect on patients outcome through a prospective multiple centers randomized controlled study to see if the stratified warming strategy can reduce perioperative hypothermia and improve patients outcome.

2. How many people will participate in this study?

This study was conducted by the Peking Union Medical College Hospital, Beijing Hospital and Xuanwu Hospital. It is expected that 800 participants will participate voluntarily.

3. What is included in this study?

If you agree to participate in the study and sign the informed consent form, you will be subject to trial-related examinations and assessments to determine suitability for participation in the study. The data we collect include demographic data, past medical history, perioperative hypothermia risk factors such as BMI, operation type, fluid therapy etc.; cognitive function evaluation; laboratory tests; current medication. If you meet the inclusions, we will evaluate your perioperative hypothermia risk and stratify into high/ moderate and low risk group. Then you will be assigned to the protective group (active warm method according to risk stratification) or the control group (traditional cotton blanket warm), which is randomly determined by the computer. The trial will last during operation time, and perioperative core temperature and blood pressure, heart rate, rehabilitation time, postoperative laboratory test and cognitive function will be recorded and evaluated. You will be followed up for 3 month and any postoperative complications will be recorded clearly

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

Although active warm strategy is widely used in advanced country, the cost cannot be afforded by every patients in China. As a result, traditional cotton blanket warm

strategy is still widely used in China. In this research, we provide active warm methods for protective group according to risk stratification, and cotton blanket warm for control group, which means these research will not increase your perioperative hypothermia risk and we can find the more cost-effective warm strategy. In addition, core temperature will be recorded in both group. If we find any patients' core temperature is lower than 34 °C for 30 min, we will upgrade warm strategy and make special record. Finally, if the patient in protective group are found to have significant improvement in postoperative condition or significantly more complications, according to the research regulations, the test can be terminated early so that no other patients can be harmed.

After you join the study, you will receive free relevant tests (cognitive screen and laboratory test), and you will be follow up for 3 month after operation.

5. What are the alternative options other than joining the trial?

If you do not participate in this study, you have the following options: continue your routine treatment (which means cotton blanket warm strategy) or participate in other research. Please consult your doctor about your decision.

6. Will my information be kept confidential?

We will keep your research records confidential as required by law. Your name, ID number, address, telephone number, or any information that directly identifies you will not be disclosed outside of this clinical study, unless required by applicable law. However, to ensure that the study meets relevant legal and regulatory requirements, your records may be reviewed.

7. Who will pay the research costs?

In this study, the active warm method will be provided free, but normal medical and nursing expenses are at your own risk.

8. What if research-related damage occurs?

These research will not increase your perioperative hypothermia risk and during research your core temperature will be recorded. If we find any patients' core temperature is lower than 34 °C for 30 min, we will upgrade warm strategy and make special record. If your health is damaged as a result of participating in this study, please inform the study doctor immediately and they will be responsible for taking appropriate treatment. The Peking Union Medical College Hospital will bear the cost of treatment and give you the corresponding compensation according to

relevant national regulations.

9. Can I withdraw from the study?

Your participation in the trial is voluntary and you can refuse to participate or withdraw from the study in any way at any stage of the trial without discrimination or retaliation.

10. Who can I contact if I have any question?

You can contact Dr. E in Dept. of Anaesthesiology in Peking Union Medical College Hospital through telephone 010-69152024 or email easyue@163.com or langjx09@163.com.

I have informed the subject of the background, purpose, steps, risks and benefits of this randomized, controlled clinical study of Systemic Prevention and Management for perioperative hypothermia, giving him/her enough time read the informed consent form, discuss it with others, and answer questions about the research. I have told the subject to contact the researcher at any time when encountering research-related questions and provide accurate contact information. The subject has been told that he/she can withdraw from the study at any time and for no reason. I have told the subject that they will receive a copy of this informed consent containing the signature of me and the subject.

Signature of researcher

Telephone

Date

I have been informed of the background, purpose, steps, risks, and benefits of this randomized, controlled clinical study of Systemic Prevention and Management for perioperative hypothermia. I have enough time and opportunity to ask questions, and I am very satisfied with the answer. I was also told who I should contact when I have questions, complaints, worries, or want to get further information. I have read this informed consent and I agree to participate in this study. I know that I can withdraw from the study at any time and for no reason. I was told that I will get a copy of this informed consent, which contains the signature of me and the researcher.

Signature of participant

Telephone

Date