

**The Informed Consent of**  
**Multi-center Clinical Trial of Lactate Clearance Guided**  
**Fluid Resuscitation in Patients With Sepsis**

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# Informed Consent

Dear Subject \_\_\_\_\_ and (or) Kin :

You are invited to participate in a study led by Nanfang Hospital of Southern Medical University: A Prospective Multi-center Clinical Trial of Lactate Clearance Guided Fluid Resuscitation in Patients With Sepsis. Please read this informed consent form carefully and make a decision on whether or not to participate in this study. When you fail to understand anything about this informed consent form, you can ask your doctor to give you detailed explanation related to it. We suggest you to discuss with your family and friends before deciding to participate in the study. If your family is participating in other studies, please inform your doctor. The background, aim, research process and other important information of this study are as follows:

## 1. Background

Sepsis is a major public health concern which affects millions of people and it lacks specific treatment at present. Early Goal-Direct therapy is considered to be effective treatment to reduce mortality, but the specific program of resuscitation is still facing many controversy.

## 2. Aim

This study plan to provide a protocolized therapy for sepsis patients requiring resuscitation and monitor vital signs closely, which aim to evaluate the efficacy and safety of Lactate Clearance Guided Fluid Resuscitation in clinic and explore the better therapy than the EGDT program to reduce sepsis mortality.

## 3. Introduction

### (1) Overview:

It is estimated that about 1128 patients will participate in this study conducted in 30 different research institutions / medical institutions, and about 100 patients of Nanfang Hospital will be enrolled.

### (2) Brief protocol

Patients who meet the criteria will be enrolled and allocated to different therapy group,  $\text{Lac}\% \geq 10\%$  Group,  $\text{Lac}\% \geq 20\%$  Group,  $\text{ScvO}_2$  Group, by central-randomized. Three groups share three same goals: the average arterial pressure, central venous pressure and urine volume. The only difference among three groups is that in  $\text{Lac}\% \geq 10\%$  Group and  $\text{Lac}\% \geq 20\%$  Group, subjects will receive the protocolized therapy to achieve target of lactate clearance, meanwhile, subjects will receive EGDT in  $\text{ScvO}_2$  Group.

### (3) Total study period

The interventions will be performed for 6 hours and followed up to 90 days after enrollment.

## 4. Risks and benefits

### (1) Risk:

- Fluid overload
- Hypovolemia

The risk of this study is equivalent to the risk of conventional treatment.

### (2) Benefits:

We hope that your participation and information can help us to explore the better therapy of sepsis and help more patients.

## 5. Information confidentiality

With the permission of you and your family and other subjects, the results of this study may be published in medical journals, but we will keep your records confidential as required by law. The subject's personal information will be kept strictly confidential, unless the relevant legal departments come up with requirements. If necessary, the government administration and the hospital ethics committee and other relevant researchers may consult your information as required.

## 6. Costs

(1) Study related inspection costs:

Study related inspection costs will be free, including all blood gas analysis, a total of about 1,200 yuan.

(2) Compensation:

You will be compensated for 100 yuan for the expenses incurred in this study (communication costs and time during follow-up).

(3) Compensation if injury occurs:

If any study related injury occurs during study period, you may receive free treatment provided by Nanfang Hospital of Southern Medical University and will be compensated according to law.

## 7. The rights and responsibilities

(1) Rights:

- All subjects are voluntary
- If you decide to participate in this study, you should sign the informed consent. If not, you can receive the routine treatment without any doubt.
- You can choose to withdraw from the study at any time without any penalties or loss of any benefit that the subject should have received.
- If we terminate the study of the subject, you can get detailed explanation.

(2) Responsibilities:

- You should provide reliable medical history and physical condition of the subject
- Inform the doctor whether the subject has participated or is currently participating in other research projects.

## 8. Contact

If you have any questions related to this study, you can call +86 20 6164 1886.

If you wish to feedback any question, comments and suggestions of the study, please send E – mail to Medical Ethics Committee of Nanfang Hospital: nfyec@163.com.

I agree to participate in the study ☐

Subject/Kin sign: \_\_\_\_\_

Relationship: \_\_\_\_\_

Phone number: \_\_\_\_\_

Date: \_\_\_\_\_

Doctor sign: \_\_\_\_\_

Hospital: \_\_\_\_\_

Phone number: \_\_\_\_\_

Date: \_\_\_\_\_