



To the patient

Information about participation in a clinical trial of patients with blood poisoning shock (septic shock) in the intensive care unit

Trial title

**Conservative vs. Liberal Approach to Fluid Therapy of Septic Shock in Intensive Care (CLASSIC)
- a randomised clinical trial**

Introduction

You have had a serious infection that resulted in you being admitted to an intensive care unit. We now ask if you want to consent to the participation in a clinical trial. The trial procedures began during the emergency care and your doctor gave permission for you to participate in the trial. You received emergency care and your condition made us unable to ask you directly if you wanted to participate in the trial.

Now that you're improving, we ask if you want to continue in the trial. You must fully understand what the trial is about and why we do it. Please read this participant information thoroughly.

You will have a conversation with the doctor or a person from the research team about the trial, where you can ask questions. You are welcome to bring a family member or a friend to the talk.

If you decide to continue your participation in the trial, we will ask you to sign a consent form. Please spend the time you need before you decide if you want to participate.

It is voluntary to participate in the trial. You can at any time and without giving a reason pull the consent without it affecting your current or future care.

Background

Blood poisoning shock (septic shock) is characterized by failure of the circulation and vital organs and it is therefore, important to improve treatment. Intravenous fluid treatment (fluid given in a drip) to improve the circulation is a frequent treatment in blood poisoning shock, but there is sparse knowledge about the optimal amount of fluid. There is research, which indicates that increased amounts of fluid may be harmful. On the other hand, there is no doubt that fluid treatment - to a certain extent - is beneficial, but we are less certain about how much to give.

Aim of the trial

We will compare two approaches to fluid treatment of blood poisoning shock; a restrictive approach (less fluid) compared to an approach that reflects common practice (more fluid).

Practical issues

You received fluid guided by one of two approaches to treatment during the entire stay in the intensive care unit for a maximum of 90 days. At the end of the trial we will calculate the amount of fluid, survival, restoration of body functions and adverse effects for the treatments. While participating in the trial, you received treatment and monitoring like all other patients with blood poison shock. The trial is conducted in 50 intensive care units in Europe, from which a total of 1554 patients will be included. A year after your admission to the intensive care unit, we will contact you with a questionnaire and a cognitive test.



Gain from participating in the trial

You will not necessarily gain from participating in the trial, but participation in the trial can help us gain important knowledge about the best treatment of blood poisoning shock. This knowledge will improve the care of future patients with blood poisoning shock. The trial is associated with minimal risks as fluids are used in the intensive care unit already and patients with the highest risk of adverse effects cannot participate.

We believe that the trial can help to better understand how we best use fluid in patients with blood poisoning shock. In this way, treatment of this group of patients can be improved for the benefit for future patients and for society.

Who can participate?

You can participate if you are 18 years of age or older and admitted or planned admitted to the intensive care unit with blood poisoning shock.

Who CANNOT participate?

You cannot participate if you have prolonged blood poisoning shock, acute burns or life-threatening bleeding.

It is the clinical doctor who decides whether participation in the trial is possible.

Interruption of the trial

You can withdraw from the trial at any time without giving any reason for this. If so, it will not affect the relationship with the doctors in the department or the treatment. You will continue to receive the care that you need.

The clinical doctors may also choose to interrupt the trial and you will receive direct notification of the cause thereof.

Disadvantages

The trial does not cause any disadvantages for you.

Adverse effects, risks and complications

The known adverse effects to the fluids are rare and consist of allergic reactions (very rare, and in general not serious), nervous system disorders (rare but severe) and salt balance disorders (rare and usually not serious).

There may be other risks of the trial, which we don't know of yet. If we suspect any adverse effects, which we haven't already told you about, we will inform you right away.

Confidentiality

All information will be treated confidentially and the trial results will be reported with full anonymity for you. The Medicines Agency, the Good Clinical Practice unit, the Sponsor and the site investigator have access to your relative's hospital files to ensure that the trial is conducted as agreed upon. These persons are subject to professional secrecy.

Funding of the trial

Initiator and sponsor of the trial is Professor Anders Perner at Rigshospitalet in Copenhagen and doctors from several intensive care units in Europe. Together they have obtained private funding from The Novo



Information about participation in a clinical trial of patients with septic shock in the intensive care unit
Conservative vs. Liberal Approach to Fluid Therapy of Septic Shock

March 12th, 2018, version 1.0

Nordisk Foundation 1,380,000 Euro and Doctor Sofus Carl Emil Friis and Wife Olga Doris Friis Fund 150,000 Euro for the conduct of the trial. The money is being used for external monitoring of the trial, data collection and remuneration of staff and a PhD student. Each trial site will receive 400 Euro per included patient to cover the costs of inclusion of trial participants and data collection. None of the investigators have financial affiliation with companies or foundations that could have interests in the outcome of this trial.

Insurance

You will be covered by the trial insurance.

Access to the trial results

When the trial is completed (expected September 2020), the results will be published in an international scientific journal. If you want information about the trial results, including any implications for you, please mark this on the consent form.

With this information we hope that you have sufficient insight into the consequences of trial participation for you to make the decision on participation. Further information about the trial can be obtained by contacting the undersigned.

Yours sincerely

Insert investigator name and contact details