**To the relatives**

**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**

Your relative is / was admitted to an intensive care unit. For this reason, we now ask you if you will give consent to his / her participation in a clinical trial. Since he / she cannot consent him / herself, we ask you on his / her behalf (proxy consent). The trial was commenced during emergency care when your relative had impaired consciousness.

Participation in the trial is voluntarily and you can refuse without it affecting the current or future care of your relative.

Before you decide if you will give proxy consent to participate in the trial, you must fully understand what the trial is about and why we conduct it. Please read this participant information thoroughly. You will have the participant information explained orally and can ask questions. Feel free to bring a family member or friend to the conversation. If you decide that your relative can continue in the trial, we will ask you to sign the attached consent form. Please spend the time you need before you decide. Your relative will be asked for consent as soon as he / she regains his / her consciousness.

**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**

Your relative receives 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, your relative will receive 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 relative's admission to the intensive care unit, we will contact him / her with a questionnaire and a cognitive test.

**Gain from participating in the trial**

Your relative 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 shocks. 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?**

Your relative can participate if he/she is 18 years of age or older and admitted or planned admitted to the intensive care unit with blood poisoning shock.

**Who CANNOT participate?**

Your relative cannot participate if he/she has 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 your proxy consent 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. Your relative will continue to receive the care that he/she needs.

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 your relative.

**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 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**

Your relative 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 your relative to make the decision on participation. Further information about the trial can obtained by contacting the undersigned.

Yours sincerely

Insert investigator name and contact details

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