For the relatives

Information about clinical trial participation for patients admitted to the intensive care unit

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Title:

The Intensive Care Platform Trial (INCEPT)

Introduction

We would like to ask you for your consent to your relative participating in a clinical trial. Your relative is in a critical condition which means he or she is unable to provide their own consent. Therefore, we ask you if, on behalf of your relative, you will give substituted consent to the participation. Because your relative's condition required acute treatment with the treatments investigated, your relative was included in the trial. Afterwards a doctor independent of the trial (called a trial guardian) assessed that your relative could continue participation, and now we would like to discuss the participation with you. Your relative will be asked for their own consent as soon as his or her condition allows for it.

Before you decide it is important that you understand what is involved and why we do the trial. Therefore, please read this participant information carefully.

You will have a conversation with a doctor responsible for the trial, where the information will be elaborated and where you can ask questions. You are welcome to bring a companion for the conversation. If you decide that your relative can continue in the trial, we will ask that you sign a consent form. You have the right to take time for consideration before you decide.

Participating in the trial is voluntary, and you can at any time stop your relative's participation without giving a reason. This will not affect other parts of your relative's treatment.

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Background

In the ICU critically ill patients with complex diseases are treated and cared for. This often involves mechanical ventilation, circulatory support, and kidney support (dialysis), and several other treatments.

These treatments are essential, but the best way to provide them is not always clear. For this reason, it is necessary to do clinical trials ensuring that the treatments benefit.

In the *Intensive Care Platform Trial* (*INCEPT*), we investigate several types of treatments for ICU patients simultaneously. The patients can participate in one or more sub-trials (called domains) at the same time. These sub-trials are described in separate information materials. The trial is done in many Danish and international ICUs.

Purpose of the trial

The purpose of *INCEPT* is to improve treatment for ICU patients.

Trial progress

Participation in *INCEPT* means that your relative is included in one or more sub-trials while they are admitted to the ICU. In each sub-trial different treatments are investigated. The treatment that you are assigned to is determined by random allocation. In some sub-trials the treatment allocation might be blinded meaning neither participants nor caregivers know which treatment the individual participant receives. Blinding is done to ensure as much objectivity as possible. After completion of a blinded sub-trial, your relative can get the information about which treatment they received.

During the admission we have obtained information from your relative's patient record about the health condition before he or she became ill and the condition and treatment throughout their present illness. We use these data to evaluate the effects and safety of the investigated treatments.

By the end of each sub-trial, we will among other things assess:

- Survival
- Serious adverse reactions to the treatments
- Duration of life supportive therapies
- Duration of delirium
- Duration of stay in hospital
- Quality of life and cognitive function

Your relative participated in the trial during their admission. Duration of the treatments is described in the information materials for each sub-trial. For each sub-trial, we evaluate patient outcomes after 1 and 3 months by accessing the patient record. Half a year after your relative participated in the trial, we will contact your relative, or possibly you, by phone to briefly ask about their quality of life and cognitive function (the ability to remember, think and learn). If we are unable to reach either your relative or you by phone, we will mail a questionnaire.

Benefit of the trial

The trial is flexible. This means that each sub-trial generally adapts and continuously learns from the obtained results. In this way, the trial benefits as many participants and future patients as possible. As we do not know which of the investigated treatments are the most effective and with fewest adverse reactions, we cannot guarantee that your relative will directly benefit from participation. But your relative's participation will contribute to improved treatment for ICU patients.

Assessment of your relative's participation in the trial

This is an emergency trial, so your relative is already participating based on a doctor's assessment. Your relative is participating, because a doctor in the ICU concluded that he or she fulfilled the criteria for participation. The doctor has also assessed if your relative could take part in one or more sub-trials.

Withdrawal of the patient's participation in the trial

You can at any time stop your relative's participation in the trial or a specific sub-trial. That will not affect other parts of your relative's treatment. The doctors in the ICU may also decide to stop your relative's participation. In that case, you or your relative will be informed about the reason. If you choose to withdraw from parts or all of the trial, we will ask for your permission to continue registration of relevant information about your relative for half a year after they participated in the trial.

Confidentiality

All information will be treated in confidentiality, and in all reports and publishing of trial results your relative will be anonymous. The Danish Medicines Agency, the Good Clinical Practice (GCP) unit and the doctor responsible for the trial have access to your relative's patient record to make sure that the trial progresses as planned. They all work under confidentiality. The handling of personal information will adhere to the General Data Protection Regulation (GDPR) and locally applicable data protection laws. Information may be shared with other researchers in anonymised form after approval from the trial management committee, or in non-anonymised form after approval from the relevant authorities.

Funding of the trial

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The above funding covers fixed expenses such as 1) salaries for researchers, project nurses, data managers and other staff directly involved in the trial, and 2) administrative expenses including those related to monitoring of the trial such as data management, data capture, safety monitoring, ethical approvals, insurances, and other regulatory requirements.

Insurance

Your relative is covered by the Danish patient insurance 'Patienterstatningen' during trial participation.

Dissemination of trial results

When a sub-trial is completed, a summary of results, including one in plain language, will be published in the official EU database of clinical trials (euclinicaltrials.eu). The summaries will be published regardless of the results. Results from each sub-trial will also be published in scientific journals and on the trial website, www.incept.dk.

Do you need more information?

We hope you are sufficiently informed to decide if your relative can continue to participate in the trial. We also recommend that you read the enclosed translations into English from The Danish National Center for Ethics: "*Your rights as a participant in a clinical trial with medical products*". If you have questions or want further information, you are welcome to contact us.

On behalf of the *INCEPT* management committee,

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