For the patient

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

EUCT-number: 2024-516208-41-00

Title:

The Intensive Care Platform Trial (INCEPT)

Your participation

You have been seriously ill and admitted to our intensive care unit (ICU). You were in a critical condition that required immediate treatment. Your condition meant that you could not decide yourself if you wanted to participate in a clinical trial. Because your condition required acute treatment with the treatments investigated, you were included in the trial. Afterwards a doctor independent of the trial (called a trial guardian) assessed that you could continue participation. Your participation was also discussed with your closest relatives.

Now that your condition is improving, we ask you if you want to continue participating in the trial. It is important that you understand what this means 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 relative for the conversation.

If you decide to 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 participation without giving a reason.

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 you have been included in one or more sub-trials while you were 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, you can get the information about which treatment you received.

During the admission we have obtained information from your patient record about your health condition before you became ill and your condition and treatment throughout your 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

You participated in the trial during your 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 without you having to do anything. Half a year after your participation in the trial, we will contact you or your relatives by phone to briefly ask about your quality of life and cognitive function (your ability to remember, think and learn). If we are unable to reach either you or your relatives 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 you will directly benefit from participation. But your participation will contribute to improved treatment for ICU patients.

Assessment of your participation in the trial

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

Withdrawal of your participation in the trial

You can at any time stop your participation in the trial or a specific sub-trial. That will not affect other parts of your treatment. The doctors in the ICU may also decide to stop your participation. In that case, you or your relatives 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 you for half a year after you participated in the trial.

Confidentiality

All information will be treated in confidentiality, and you will be anonymous in all reports and publishing of trial results. The Danish Medicines Agency, the Good Clinical Practice (GCP) unit and the doctor responsible for the trial have access to your 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

INCEPT is funded by the Novo Nordisk Foundation (approx. 4.020.000 EUR) and 'Sygeforsikringen "danmark"' (approx. 980.000 EUR) and supported by 'Savværksejer Jeppe Juhl og hustru Ovita Juhls Mindelegat' (approx. 134.000 EUR), 'Grosserer Jakob Ehrenreich og Hustru Grete Ehrenreichs Fond' (approx. 27.000 EUR) and 'Dagmar Marshalls Fond' (approx. 13.000 EUR). Funding of specific sub-trials is described separately. The funders are not involved in the design, conduct, analyses or reporting of the trial, and they do not have ownership of results.

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

You are 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 you want to continue participation 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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