Information sheet for participant: INCEPT – albumin substudy

CTIS number: 2024-516208-41-00
Title of the clinical trial: The Intensive Care Platform Trial (INCEPT)
Substudy (domain): INCEPT – albumin

Dear participant,
you are being asked to provide consent for participation in the INCEPT – albumin substudy because you were treated in the intensive care unit and were diagnosed with shock during your stay.
This information sheet provides you with information about the clinical study. Please read the information carefully. Do not sign the consent form until you have received answers to all your questions and understand the study.

What is shock?

Shock is a serious circulatory disorder that may occur as a result of severe infection, major blood loss, or heart failure. It is a common reason for intensive care treatment

What is albumin and why is this study needed?

Albumin is a human plasma protein used in the treatment of shock to support circulation. Although albumin may improve circulation, studies have not yet clearly shown whether it also improves treatment outcomes.

What is the purpose of the study?

The purpose of this study is to compare the use of albumin with standard treatment without albumin and to evaluate their safety and effectiveness in intensive care patients.

What treatment will I receive in the study?

All study participants are randomised, meaning they are assigned by chance to one of two study groups, similar to flipping a coin. You have a 50% chance of being assigned to either group:

- **First group:** participants will receive albumin.
- **Second group:** participants will not receive albumin.

If the treating physician considers albumin necessary for your treatment, it will be given regardless of which study group you belong to.

Is albumin administration safe?

Albumin is a medicine with well-documented use and is generally considered safe. The most common side effects are nausea and fever. Serious allergic reactions occur very rarely. Unexpected side effects or complications may still occur.

How long will the INCEPT – albumin substudy last?

Each participant will receive the study-assigned treatment for as long as they remain in the intensive care unit, for a maximum of 90 days.
The INCEPT – albumin substudy will continue until sufficient data have been collected to allow reliable conclusions to be made. The exact end date is not yet known, but the study is expected to end in 2028. Up to 10,000 participants will be enrolled worldwide.

How is the INCEPT – albumin substudy funded?

The INCEPT – albumin substudy is funded by the Independent Research Fund Denmark.

Informed consent form for participant: INCEPT – albumin substudy

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PARTICIPANT'S CONFIRMATION

By signing this consent form, I confirm that I have been informed about the study and understand its purpose, methods, risks, and possible health-related harms. By signing this consent form, I consent to participate in the INCEPT trial and the INCEPT – albumin sub-study in accordance with the information provided in both information sheets. I confirm that:

- I have read the INCEPT and INCEPT – albumin information sheets, version 1.1, dated 16 August 2026, and I have understood the information provided therein.
- I have had the opportunity to consider the information, discuss the study, ask questions, and have received satisfactory answers to my questions.
- I have received a signed copy of the information sheet for myself.

I voluntarily agree to participate in the study and acknowledge the following:

1. Participation in the study may involve risks.
2. For the purposes of the study, the study personnel will collect my health data from my paper medical records, electronic medical records, the Health Information System (digital health record), and, if necessary, the death registry, to the extent required for conducting the study, assessing safety, and analysing the study results.
3. Data and clinical information collected during the study will be treated confidentially and my data will be used in pseudonymised form.
4. Members of the study team and authorised persons may access my study-related medical data as necessary for conducting the study, quality control, and oversight.
5. If I later withdraw from the study, the study intervention will stop. Data collected until then will be retained in de-identified form in accordance with study requirements.

I understand that participation in the trial is voluntary and that I may withdraw my consent, without providing a reason, at any time by informing the study team. I understand that withdrawal of consent will not have retrospective effect.

Participant's name: _____

Participant's signature: _____ Date of signature: _____

CONFIRMATION OF PHYSICIAN OBTAINING CONSENT

I hereby confirm that the participant has received verbal and written information about the clinical study. In my opinion, sufficient information has been provided to allow an informed decision. The participant had the opportunity to discuss the study and ask questions.

Name of physician obtaining consent: _____

Physician's signature: _____ Date of signature: _____