Information sheet for participant: INCEPT – thromboprophylaxis substudy

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

Dear participant,
you are being asked to provide consent for participation in the INCEPT – thromboprophylaxis substudy because you were treated in the intensive care unit and required low-molecular-weight heparin for the prevention of thrombosis.
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 thrombosis?

Thrombosis means that a blood clot forms inside a blood vessel, blocking normal blood flow and potentially causing serious complications. Thrombosis occurs in approximately one out of ten intensive care patients.

What is low-molecular-weight heparin and why is this study needed?

Low-molecular-weight heparin is a medicine used to prevent and treat blood clots. It is also called a blood thinner because it helps blood flow more easily, reducing the risk of new clots forming and preventing existing clots from growing.

The dose of the medicine must be high enough to prevent blood clots, but not so high that it increases the risk of bleeding. At present, it is not known which dose is best for intensive care patients, which is why different doses are used in different hospitals and situations.

What is the purpose of the study?

The INCEPT – thromboprophylaxis substudy compares three different blood thinner doses to identify the safest and most effective dose for intensive care patients.

What treatment will I receive in the study?

A computer randomly assigns participants into one of three groups receiving different doses of low-molecular-weight heparin: a) a low fixed dose, b) a medium fixed dose, c) a weight-adjusted dose. You have received the study-related treatment during your stay in the intensive care unit. No procedures different from standard intensive care treatment will be performed because of the study.

Is low-molecular-weight heparin safe?

The most common side effects are bleeding and reactions at the injection site. Very rarely, serious allergic reactions or a decrease in platelet count may occur. Other unexpected side effects or complications may also occur, although this is very unlikely. If this happens you will receive appropriate treatment.

How long will the INCEPT – thromboprophylaxis substudy last and how is it funded?

The INCEPT – thromboprophylaxis substudy will continue until reliable conclusions can be made from the study results. The exact end date is not yet known, but the study is expected to end in 2028. Funding for the study comes from the overall INCEPT research grant.

Informed consent form for participant: INCEPT – Thromboprophylaxis substudy

CTIS number: 2024-516208-41-00

Title of the clinical trial: The Intensive Care Platform Trial (INCEPT)

Substudy (domain): INCEPT-Thromboprophylaxis

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 – Thromboprophylaxis sub-study in accordance with the information provided in both information sheets. I confirm that:

- I have read the INCEPT and INCEPT – Thromboprophylaxis study 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: _____