
General information sheet for participant's representative: INCEPT

CTIS number: 2024-516208-41-00

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

Dear participant's representative,

you are receiving this information sheet and informed consent form because your loved one is being treated in the intensive care unit due to a serious illness. Their condition was critical and required urgent treatment. Because of this, it has not been possible to inform them about the study or ask for their consent directly.

We are therefore asking you to provide consent for your loved ones' continued participation in the study. This information sheet explains the purpose and procedures of the study so that you can make an informed decision. Please read the following information carefully. Do not sign the consent form until you have understood the information provided and received answers to all your questions.

Participation in the study is voluntary. Both you and your loved one have the right to stop participation in the study at any time without giving a reason.

Why is this study being conducted?

Intensive care units treat critically ill patients who often require complex treatments such as mechanical ventilation, circulatory support, dialysis, and many other treatment methods and medications. Although these treatments are necessary, it is not always known which treatment is the safest and most effective.

The INCEPT intensive care platform trial studies several intensive care treatments that are already in clinical use at the same time. The study consists of several substudies (called domains), and participants may take part in one or more domains simultaneously. More detailed information about each substudy is provided in separate information sheets.

What is the purpose of the study?

The purpose of this study is to improve the quality of treatment and outcomes for intensive care patients.

Who is conducting the study?

The INCEPT study is conducted in several countries and hospitals around the world. The study is led by Rigshospitalet, Copenhagen University Hospital in Denmark. In Estonia, the study is conducted at Tartu University Hospital, North Estonia Medical Centre, and East Tallinn Central Hospital.

What does participation in the study mean?

Participation in the INCEPT study means that your loved one may be included in one or more substudies during their stay in the intensive care unit, where treatment methods already used in intensive care are being studied.

Each substudy investigates different treatment methods. Which substudy your loved one is included in depends on their medical condition, illnesses, and treatment needs.

The substudies use randomisation, meaning that the specific treatment method assigned to your loved one is chosen by chance. All treatment methods used in the study are considered appropriate, but it is currently not known which is the safest or most effective. This is why the study is needed.

Some substudies also use blinding. This means that neither you, your loved one, nor the clinical team knows which treatment or medication dose the participant receives. This helps ensure the most objective assessment of treatment effectiveness possible. If you wish, you may find out which treatment your loved one received after the study has ended.

Participation in the study does not require any additional actions from you or your loved one. Information needed for the study will be collected from your loved one's medical records. You or your loved one may be contacted later if necessary.

What information about my loved one will be collected? How and why?

As part of the study, information about your loved one's health, treatment, and course of illness will be collected from their paper medical records (for example treatment charts), electronic medical records (for example laboratory results and clinical notes), and the Health Information System (for example hospitalisation data). These data are used to evaluate the effects and safety of the treatment methods studied. This includes information about survival, serious side effects, use of life-support treatments, length of hospital stay, quality of life, and cognitive function.

In each substudy, participants' condition will be assessed:

- after 1 and 3 months using medical record data (you do not need to do anything for this);
- after 6 months, you or your loved one will be contacted by telephone and asked brief questions about their quality of life and cognitive function (memory, thinking, and learning ability). If telephone contact is unsuccessful, a questionnaire may be sent by post or e-mail.

Some data will also be collected from medical records.

Collection of these data is necessary to evaluate the safety and effectiveness of the treatments studied and to ensure that the study complies with applicable laws and ethical requirements.

Does participation in the study cost anything?

Participation in the study is free of charge. Your loved one's regular health insurance remains valid during the study, and additional study insurance is provided if necessary.

What does my loved one gain from participating in the study?

The study compares different treatment methods to identify the safest and most effective treatment options for intensive care patients. During the study, the results are continuously analysed and the study may be adjusted if needed, for example by stopping the use of less effective treatments. This helps make the study as safe and beneficial as possible for both current and future patients.

At present, it is not known which treatment method is the safest and most effective, so direct benefit from participation cannot be guaranteed. However, your loved one's participation will help improve the treatment of intensive care patients in the future.

Participants will not be paid for taking part in the study.

Does my loved one have to participate in this study?

No. Participation in the study is voluntary, and you decide whether to continue your loved one's participation and study-related interventions in one or more substudies. If you have questions, you may always contact the study team, who will discuss them with you.

- If you decide that your loved one will not participate or wish to withdraw later, you may do so at any time without giving a reason, even after initially giving consent.
- If you or your loved one withdraws from the study, study-related interventions will stop immediately. Your loved one's treatment will continue according to the best current clinical practice and treating physician's recommendations.
- If you withdraw from the study, data collected before withdrawal will still be used for study purposes in a way that does not allow identification of your loved one as an individual. We will also ask your permission to collect follow-up data from registries for up to six months.

How will my loved one's personal and health data be protected and processed?

Your loved one's data will be processed in accordance with data protection legislation. Your loved one's personal data will initially be collected in identifiable form. For analysis, coded (pseudonymised) data will be used. Their name and other identifying details will be replaced with a special study code, and further processing will take place using this code. Documents concerning your loved one's treatment are confidential. Only study staff and authorised personnel can identify them.

Data related to your loved one's participation in the study will be stored on a secure server at the study centre in Denmark for 25 years after completion of the final substudy. Only investigators at the Estonian study sites will have access to the code key linking the code to your identity. The data controller is Rigshospitalet, Copenhagen University Hospital, Denmark.

The study sponsor, Copenhagen University Hospital (Rigshospitalet), and persons authorised by the sponsor, such as monitors and auditors, as well as employees of competent national authorities overseeing the study (the State Agency of Medicines and ethics committees), may require direct access to your medical records in order to ensure that the study is conducted properly and in accordance with applicable laws and ethical requirements. All such persons are obligated to protect the confidentiality of your personal data in accordance with the law.

During the study, information about your loved one's participation will be entered into their electronic medical record and transferred to the Health Information System. Your loved one has the right to access their data and request corrections if needed. As part of the usual functioning of the Estonian healthcare system, information related to their participation, procedures, and treatment monitoring may be visible to other healthcare professionals through the Health Information System. If your loved one wishes, they may restrict access to their health data.

Information collected in the study may be shared with other researchers in anonymised form after approval from the study management committee, or in identifiable form after approval from the relevant authorities.

The independent ethics committee operating under the State Agency of Medicines has reviewed and approved this study after evaluating its ethical acceptability with regard to participants' dignity, rights, safety, and wellbeing.

If you decide to withdraw from the study during participation, data and analyses already collected will continue to be used for research purposes in a way that does not allow identification of your loved one as an individual.

How is the study funded?

The INCEPT study is funded by the Novo Nordisk Foundation and 'Sygeforsikringen "danmark"', with additional support from Savværksejer Jeppe Juhl og hustru Ovita Juhls Mindelegat, Grosserer Jakob Ehrenreich og Hustru Grete Ehrenreichs Fond, and Dagmar Marshalls Fond. Funding for specific substudies is described in separate substudies information sheets. The funders have no role in the design, conduct, analysis, or reporting of the study and have no ownership rights to the study results. The funding covers study-related personnel and administrative costs, including monitoring, data management, safety oversight, and participant insurance.

Will we be informed about the study results?

When a substudy is completed, a summary of the results, including a plain-language summary, will be published in the official European Union clinical trials database (euclinicaltrials.eu). Summaries will be published regardless of the study results.

Results from each substudy will also be published in scientific journals and on the study website: www.incept.dk

Study results may also be presented at scientific conferences or published as scientific articles in medical journals.

All results will be presented in a general form and will not contain information that could identify your loved one's personally. If you wish, you may request additional information about the study results from the study team.

In summary, what happens if I decide that my loved one can participate in the study?

- You sign the consent form and keep one copy for yourself.
- Study-related interventions will continue.
- The interventions for each substudy are described in the relevant information sheets.
- Follow-up data collection from registries will continue.
- After six months, a member of the study team will contact you or your relative to ask brief questions about their quality of life and cognitive function (memory, thinking, and learning ability).
- Your loved one's data will be collected and securely stored by the study team in accordance with data protection principles.
- You or your loved one may at any time withdraw from any remaining stages of the trial and from any further data collection in one or more sub-studies.
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Additional information

If you wish to discuss any aspect of the study, please contact us using the details below. Members of the study team will be happy to discuss the study methods and answer your questions.

For questions related to the study, please contact the Estonian national investigator:

Name: Hanna Kadri Laas, MD

E-mail: hannakadri.laas@kliinikum.ee

Telephone: +37259000110

If you have questions about the rights of study participants, please contact the Research Ethics Committee of the State Agency of Medicines:

E-mail: ethics@ravimiamet.ee

Telephone: 7374140

If necessary, you may also submit a complaint to the Estonian Data Protection Inspectorate:

E-mail: info@aki.ee

Telephone: +37256202341