The Intensive Care Platform Trial (INCEPT)

Sweden



National appendix

National appendix version and date
Version 1.2, 2026-04-01

Corresponding core protocol version and date
Version 1.5, 2026-04-01

Website: www.incept.dk

Applicable core protocol registration numbers
European Union Clinical Trials Information System (CTIS) EUCT number: 2024-516208-41-00.
ClinicalTrials.gov identifier: NCT06667999.
Universal Trial Number: U1111-1313-8171.

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1 | Administrative information

1.1 | Protocol and national appendix structure

This is a national appendix to the *Intensive Care Platform Trial (INCEPT)* core protocol. Everything described in the version of the core protocol listed on the front page applies except where explicitly stated otherwise. This national appendix only covers details that are specific to this country and not otherwise covered by the *INCEPT* core protocol. The national appendix should be read along with the core protocol.

1.2 | National coordinating centre

National coordinating centre
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A list of national coordinating investigators in all participating countries will be made available on the INCEPT website prior to first inclusion in each country and continuously updated.

2 | Abbreviations

4AT: *4 A's Test delirium assessment tool*
CTIS: *Clinical Trials Information System*
eCRF: *electronic case report form*
EU: *European Union*
EUCT number: *European Union Clinical Trials Information System (CTIS) number*
GCP: *Good Clinical Practice*
HRQoL: *health-related quality of life*
ICU: *intensive care unit*
INCEPT: *the Intensive Care Platform Trial*

3 | Screening, inclusion, and informed consent procedures

The following section contains specific procedures that apply for Sweden in addition to the generic principles outlined in the core protocol, including the use of a modular approach to the informed consent procedure with information only given for the domains that are relevant for a specific participant.

Swedish informed consent procedure
First, intensive care unit (ICU) patients fulfilling all platform inclusion criteria and no exclusion criteria will be screened and randomised to domains, for which they fulfil all domain-specific eligibility criteria, by trained trial staff. As soon as possible hereafter, informed consent for continuation in the platform trial (including all applicable domains) will be obtained from the participant, as he/she is physically and mentally recovered to receive information about the trial and to give written informed consent. All informed consents will be obtained by medical doctors trained and certified in the trial protocol and follow all applicable regulations.

For the relatives, oral information will be given either in person or by phone call, to inform that the participant has been included in a trial.

Informed consent will be obtained as soon as the participant's condition is stabilised, treatment of the underlying conditions is initiated, and the participant's cognitive state has improved sufficiently for them to understand the information and make a decision about participating in the trial. If there is doubt about the participant's mental status, evaluation of the participant's capacity to consent to the trial will be conducted using the validated 4 A's test (4AT) delirium assessment tool [1]. A score greater than 0 indicates possible cognitive impairment and, therefore, insufficient cognitive function to provide informed consent. Consent will only be obtained if the 4AT score is 0. Every contact and assessment of the participant's ability to consent, including the score of the 4AT, will be documented in the medical record. The assessment of consent capacity will be conducted by the principal investigators or their delegate, such as another investigator or sub-investigator who is a physician, or by any physician who has been informed, trained, and has signed an agreement with the principal investigator for the trial to conduct informed consent. For participants, both oral and written information will be given preferably in person by a medical doctor trained and certified in the trial protocol. If this is not possible (e.g., the participant has been discharged to another hospital without participating sites), we will inform and collect consent from the participant by phone call and written or electronic signature on the consent form.

Additionally, if a participant is not able to provide consent, the investigator will seek consent from the participant's legally designated representative immediately after inclusion and stabilisation of

the participant. If there is no legally appointed representative, the investigator will initiate the legal procedure to have such a representative appointed without undue delay. If the participant regains sufficient cognitive function before a legally designated representative could be appointed in accordance with national law, and can either provide or refuse consent, the process for the legally designated representative will be terminated.
The consent will be reassessed at the time of appointment of the legally designated representative from both the representative and the participant if they have regained sufficient cognitive function as previously described. If the participant dies before it has been possible to obtain consent or before a legally designated representative is appointed, the participant will remain in the trial.

Of note, all consenting parties will be provided with written and oral information about the platform trial (including all relevant domains) allowing them to make an informed decision about participation in the trial. Written information and the consent forms will be subject to review and approval by the applicable competent authorities (e.g., the relevant ethical committees). The written information material will be in modular format and consist of general information about *INCEPT* and additional information sheets about all relevant domains. The informed consent procedure will be common and simultaneous for *INCEPT* including all applicable domains, with explicit, written informed consent to each specific domain using separate informed consent forms, and with consent to one or more domains constituting consent to *INCEPT* including all elements that are common between domains. All consent forms will be signed by the consenting party and the medical doctor who has provided trial information for the consenting party. We will emphasise that the consenting party has at least 24 hours to decide whether to give consent or not. The consenting party can, at any time and without further explanation, withdraw consent to continued participation in the platform trial or specific domains.

Trial personnel
The screening will be done by trained trial staff in collaboration with the treating clinical doctor, who ultimately decides if a patient can be enrolled in the trial and individual domains. When a candidate patient is identified, a member of the trained trial staff will screen the patients in the electronic case report form (eCRF). Collection of informed consent will be performed by medical doctors who are trained and certified in the trial protocol. If questions arise during the informed consent procedure, coordinating trial staff (including the sponsor) can be reached through the 24-h trial hotline. All medical doctors with consent functions in the *INCEPT* trial will be trained and approved according to *Good Clinical Practice* (GCP) guidelines before engaging in the trial.

4 | Discontinuation and withdrawals

The core protocol outlines the procedure for handling discontinuations and withdrawals in *INCEPT* according to the applicable Danish regulations. The same procedure applies in Sweden.

5 | Outcomes and safety

5.1 | EQ-5D-5L value set

For the EQ-5D-5L instrument [2] used to assess health-related quality of life (HRQoL) at day 180, we will use the Swedish national EQ-5D-5L national value set [3] for participants enrolled in Sweden to calculate EQ-5D-5L index values for the primary analyses.

5.2 | Safety outcomes

The *INCEPT* core protocol outlines the handling of safety outcomes in *INCEPT* domains based on European Union (EU) regulations [4] for the assessment of safety outcomes for pharmacological interventions (investigational medicinal products); this procedure applies to Sweden with no country-specific adaptations and no additional collection or reporting of additional safety data.

6 | Other considerations

Insurance

Trial participants in Sweden are covered by the *Patientförsäkringen [5]* and *Läkemedelsförsäkringen [6]*.

7 | Summary of changes

This section summarises all changes to the national appendix after initial submission for approval.

Version 1.2, 2026-04-01:

- Updated to change core protocol version.

Version 1.1, 2026-02-11:

- The procedure about providing informed consent within seven days is deleted, and it is added that the investigator will seek consent from the participant´s legally designated representative immediately after inclusion and stabilisation of the participant and without undue delay.

Version 1.0, 2025-12-08: first version submitted for approval.

8 | References

1. Johansson YA, Tsevis T, Nasic S, Gillsjö C, Johansson L, Bogdanovic N, et al. Diagnostic accuracy and clinical applicability of the Swedish version of the 4AT assessment test for delirium detection, in a mixed patient population and setting. BMC Geriatr. 2021;21(1):568.
2. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011;20(10):1727–36.
3. Sun S, Chuang LH, Sahlén KG, Lindholm L, Norström F. Estimating a social value set for EQ-5D-5L in Sweden. Health Qual Life Outcomes. 2022;20(1):167.
4. EudraLex - EU Legislation. Risk proportionate approaches in clinical trials - Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use. https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10 en2017 [Vol 10 – Clinical Trials Guideline 2017].
5. Information about the Swedish patient insurance https://lof.se/patient/lag-och-villkor/forsakringsvillkor-patientforsakring: Landstingens Ömsesidiga Försäkringsbolag; [2025/11/10].
6. Läkemedelsförsäkringen-insurance for drug-related injuries https://lff.se/a-unique-type-of-insurance/: Läkemedelsförsäkringen; [2025/11/10].