The Intensive Care Platform Trial (INCEPT)

Iceland



National appendix

National appendix version and date
Version 1.3, 2026-04-01

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

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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
Landspítali - The National Hospital of Iceland
Svæfinga-og gjörgæsludeild / Department of Anaesthesiology and Intensive Care Medicine
Hringbraut, 13C
101, Reykjavik, ICELAND
Phone +354 5431000
Email: martin@landspitali.is

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

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*
INCEPT: *the Intensive Care Platform Trial*

3 | Screening, inclusion, and informed consent procedures

The following section contains specific procedures that apply for Iceland 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.

Icelandic informed consent procedure
First, 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. Enrolment in *INCEPT* including all domains will occur without prior informed consent according to the criteria in the applicable EU regulation (No 536/2014)(1) that are detailed in the *INCEPT* core protocol. As soon as possible hereafter, informed consent for continuation in the platform trial (including all applicable domains) will be obtained from the participant's legally designated representative (in Iceland the closest relative). For this we will use the relative listed in the medical record as the closest relative. If none is listed, we will ask the one which the clinical team consider the nearest relative. If there are more and disagreement arises, we will ask them to obtain consensus. If this cannot be obtained, we will stop the intervention and ask for allowance continuing data registration and follow-up using specific consent forms for the use of already collected data and for continued data collection and follow-up.

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 video call according to the relative's preferences. Video calls, where used, will be individual, direct, and with simultaneous dialogue following adequate identification of the participant and relatives, and the right to confidentiality will be ensured by ensuring that all involved parties are in a place and time where they can talk privately prior to discussing the trial. Relatives may be contacted by regular phone calls to arrange the meeting in person or via video call, according to personal preferences.
The relative has the right to bring a companion. If informed by video call, we will arrange a time and date for a video conversation with a medical doctor who is trained and certified in the trial protocol and certified in obtaining informed consent. During this conversation, we will arrange how to send the written information to the relative (i.e., via Signet Transfer, email or by physical mail). We will encourage the relative to read the written information before the next conversation. We will also encourage the relative to bring a companion; in this case, the video conversation will be held with the video call on speaker. After we have informed the relative about the trial, we will ask the relative to return the signed consent form by post or electronically via Signet Transfer.

Participants will be asked for informed consent as soon as they are able to 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 video call (as described above). Either way, the participant has the right to bring a companion to the conversation. This conversation may similarly be arranged by contact through regular phone calls, and the participants can choose to receive the oral information in accordance with personal preferences.

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. If this occurs, we will stop the intervention and ask for allowance continuing data registration and follow-up using specific consent forms for the use of already collected data and for continued data collection and follow-up.

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 single 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 can be reached by local trial staff through the 24-hour 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 regulations and principles apply for Iceland, except for discontinuations and withdrawals because of lack of consent where the following will apply.

Lack of consent from the relatives.
Procedures 1 to 3 cover the likely different scenarios with the timelines.

1. There are no relatives or contact information for these in the hospital files. If no relatives (or contact information) are identified 7 weekdays after randomization, the trial interventions and data collection will stop.
2. There are relatives with contact information in the hospital files, but they do not come to the hospital. We will try to make contact every second/third weekday and document this in the eCRF. If no contact has been made to the relatives after 3 attempts (7 weekdays), the trial interventions and data collection will stop.
3. Relatives have been informed in person or by video-link and have no objection to participation, and the information sheets have been handed over in person or send, but they have not returned the signed consent form. We will contact the relatives 1-2 times per week and document this in the eCRF. If the relatives have not handed, mailed or electronically signed the signed consent form within 30 days, the trial interventions and data collection will stop.

If the participant provides written informed consent at any time during the above processes, we will stop the consent process for the relatives.

If the trial interventions and data collection are stopped based on the above scenarios, we will fully de-identified the participant in the eCRF and use in the analyses the fully de-identified data collected to protect the validity of the trial.

The participant cannot consent.
If the participant cannot provide informed consent 30 days after randomization and the relatives have not provided consent at this time point, we will stop the trial interventions and data collection. We will fully de-identified the participant in the eCRF and use the de-identified data collected up to that time point (30 full days) to protect the validity of the trial.

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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 Danish national EQ-5D-5L national value set (3) for participants enrolled in Iceland to calculate EQ-5D-5L index values for the primary analyses as no Icelandic value set is currently available.

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 Iceland with no country-specific adaptations and no additional collection or reporting of additional safety data.

6 | Other considerations

Insurance

Trial participants in Iceland are insured by the Icelandic law about patient insurance (111/2000)(5).

7 | Summary of changes

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

Version 1.3, 2026-04-01:

- Updated to match core protocol version and minor formatting changes.
- Fixed error in date in summary of changes (section 7) for version 1.2.

Version 1.2, 2026-03-15:

- Describes how already collected data, continued data collection, and follow-up will be handled by using specific consent forms for this purpose. Furthermore, it elaborates how participants with delayed consent will be handled (discontinuation and withdrawal), including timeline for stopping of the interventions, further data collection and de-identification of the participants in the eCRF and use of de-identified data in the analyses.

Version 1.1, 2026-02-18:

- Elaborates how relatives are defined, and how the informed consent procedure will be if disagreement between relatives occur.

Version 1.0, 2025-12-17: first version submitted for approval.

8 | References

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