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Dear friends and colleagues,

EMPRESS started recruiting June 26, 2025, and the first patient was included on June 28, 2025. To date, we have included more than 60 participants across 5 actively recruiting Danish sites: Rigshospitalet 4131 (ICU), Aalborg (ICU), Kolding (ICU), Odense (ICU), and SUH Køge (ICU).

In the coming months, we plan to initiate additional

Danish sites, including Hvidovre (ICU), Hvidovre (Infectious Diseases), Rigshospitalet (Infectious Diseases), Aarhus Nord (ICU), Aarhus East (ICU), Gødstrup (ICU) and Randers (ICU).

In parallel, international start-ups are progressing in Sweden (national PI: Frederik Sjövall), Iceland (national PI: Martin Ingi Sigurðsson), and New Zealand/Australia (national PI: Paul Young).

At a glance:

Participants included to date: 63

Top recruiter: Aalborg (ICU); 21

Active sites: 5 (DK)

Next steps: initiation of additional Danish sites, and submission of application to get Sweden, Iceland and New Zealand approved.

eCRF updates & support

If you encounter issues of any kind (access, role permissions, edit checks, or unexpected queries), the hotline is open 24/7: +45 3545 0606 and we are available anytime at empress@cric.nu. When reporting, please include the patient ID (if applicable), the page name, and a screenshot—this helps us replicate and resolve potential issues within one cycle.

Often asked questions in EMPRESS

Q: Can we escalate to a broader agent (e.g., a carbapenem) in a participant allocated to piperacillin/tazobactam?

A: Escalation to a non-allocated agent constitutes a protocol violation and should be avoided unless clinically required for patient safety (e.g., documented resistance, severe deterioration). The protocol does not mandate a specific combination regimen; if broader coverage is needed, you may add agents to the allocated treatment per local guidelines rather than replacing it. If broader Gram-positive is needed Clindamycin could be added, if broader Gram-negative coverage is needed Ciprofloxacin could be added with in combination with the allocated study drug.

Q: Is a patient eligible upon ICU readmission if they previously received piperacillin/tazobactam during a different admission/episode weeks earlier (outside the trial site)?

A: Yes, potentially. If this is a new suspected infection episode, the prior antibiotics were given weeks earlier for an independent admission/indication, and the patient otherwise meets all current inclusion criteria (including any re-enrolment rules), the patient may be included.

Q: A participant allocated to piperacillin/tazobactam now needs empirical treatment again (e.g., aspiration) within 30 days of enrolment. Should we switch or remain on the allocated arm?

A: Remain on the allocated arm within the protocol-defined allocation period (30 days), unless there is a clear safety reason to change (e.g., allergy, intolerance, culture-proven resistance). Document clinical reasoning and any deviations in the eCRF.

Q: If erythromycin is given at prokinetic doses to promote gastric emptying, should it be recorded as “other antibiotics” in the eCRF?

A: No. Prokinetic-dose erythromycin is not administered as anti-infective therapy; therefore, it does not need to be recorded as concomitant antibiotic therapy. If your eCRF has a field for other concomitant medications, you may record it there per local practice.

The team behind EMPRESS

EMPRESS is run by a collaborative, multidisciplinary group: Nick Frørup Meier (MD, PhD-student), Morten Hylander Møller (MD, Professor), Anders Granholm (MD, postdoc), Maj-Brit Nørregaard Kjær (CCRN, PhD), Anders Perner (MD, Professor), Milda Grigonyte-Daraskeviciene (MD, PhD-student), Aske Tøgern (MD, PhD-student), and Jehad Ahmad Barakji (MD, PhD-student). Thank you to every investigator, coordinator, and bedside clinician who is screening, consenting, randomising, and capturing high-quality data.



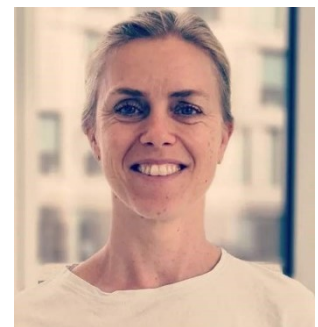
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With collegial regards,

Nick Frørup Meier, Morten Hylander Møller, Anders Granholm, Maj-Brit Nørregaard Kjær and Anders Perner

On behalf of the EMPRESS Coordinating group