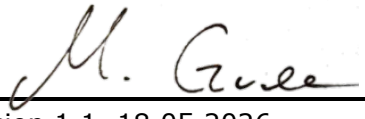
1. Original Title and general information

Project name	Prehospital Point-of-Care Testing to Support Decision-Making in Alternative and Non-Conveyance Pathways: A Matched Parallel Cluster-Randomized Trial
Project Acronym	The pre-POCT–Non-Conveyance trial
Sponsor	Central Denmark Region, Denmark
Principal Investigator	Martin Faurholdt Gude, MD, PhD Prehospital Emergency Medical Services (Præhospitalet), Olof Palmes Allé 34, 8200 Aarhus N
Investigator signature	
Protocol version and date	Version 1.1, 18.05.2026
Study coordinators	Mille Svenstrup Jensen, BSc Nicoline Buelund Jensen, BSc

2. Purpose

Rationale, background, problem formulation, hypothesis and endpoints

Rationale

A substantial proportion of patients transported by EMS are discharged shortly after hospital arrival without requiring advanced diagnostics or treatment. These short, low-value admissions contribute to ED crowding, inconvenience to patients, and increase healthcare costs. Improving prehospital decision-making may reduce avoidable admissions while maintaining patient safety.

Point-of-care testing (POCT) may be a key component in this strategy. By providing rapid biochemical analyses directly on scene, POCT can support more informed decisions during telemedical consultation with the EMDC physician. This may help ambulance clinicians and physicians assess whether selected patients can safely remain at home, thereby potentially reducing unnecessary transports and optimizing resource utilization.

Background

Over the past decades, there has been an increase in the use of prehospital emergency medical services (EMS) and emergency departments (EDs).[1–3]

In Denmark, EMS activity has grown considerably, with non-conveyance becoming a more frequent outcome of prehospital assessment.[4–7]

This shift reflects broader international trends driven by ageing populations, limited access to primary care, and an increasing number of non-urgent patients entering the emergency healthcare system.[2,5–8]

Non-conveyance can help reduce ED crowding, improve resource utilization, and maintain capacity for time-critical emergencies.[6,7,9,10] However, patient safety must be ensured when discharging patients on scene. International studies show that within 24–48 hours, 2.5–6.1% of non-conveyed patients recontact EMS, 4.6–19.0% visit the ED, 1.0–3.3% are hospitalized, and mortality ranges from 0.2 to 3.5%.[11]

A recent Danish register-based study in the Central Denmark Region, which included all EMS non-conveyance cases over a two-year period, found that 4.7% of non-conveyed patients were reassessed by EMS, 4.9% were admitted to hospital, and 48-hour mortality was 0.08%.[12] Increased risk for reassessment and readmission was observed in older patients, males, those with abnormal vital signs, and specific complaints such as ear, nose, and throat problems, seizures, non-traumatic bleeding, and psychiatric presentations.[12] These findings indicate that current non-conveyance

practice is relatively safe, yet most EMS patients are still transported to hospital.[12] Whether more patients could safely remain at home remains an open question.

POCT may improve patient selection for non-conveyance. Despite widespread hospital use, prehospital POCT has been insufficiently studied in this context. By providing rapid results on electrolytes, renal function, inflammatory markers, and hematology, POCT may support decisions that reduce unnecessary admissions while maintaining safety. This cluster randomized trial will evaluate the implementation of POCT in ambulance-based assessment and describe its association with admission patterns, revisits, and safety outcomes.

Hypothesis

We hypothesize that prehospital POCT can be implemented in routine ambulance-based assessment of clinically stable patients considered for hospital conveyance, and that POCT-supported assessment can be performed, documented, and integrated into telemedical consultation with the EMDC physician. Clinical outcomes, including non-conveyance, hospital contacts after non-conveyance, and mortality, will be evaluated as exploratory safety and effectiveness outcomes to inform a future definitive trial.

Objectives

Primary Objective

To evaluate the feasibility of implementing prehospital POCT in routine ambulance-based assessment of clinically stable patients initially considered for hospital conveyance.

Secondary Objectives

- To estimate each step in the implementation pathway, including POCT attempt, successful POCT measurement, documentation of a valid result, and availability of a valid result before the final conveyance decision.
- To compare non-conveyance between intervention and control clusters.

- To compare hospital admission within 24 hours among non-conveyed patients between intervention and control clusters.
- To compare the proportion of short-stay hospitalizations (<6 hours without advanced intervention (procedures or medication) or CT/MR imaging).
- To compare total hospital length of stay between groups.
- To compare intensive care unit (ICU) admission rates.
- To compare 30-day mortality between groups.
- To estimate the intra-cluster correlation coefficient (ICC) for non-conveyance and selected clinical outcomes in this EMS setting.

Endpoint Definitions

Primary Endpoint

Implementation of prehospital POCT, defined as the proportion of intervention-cluster attended patient encounters within the study population in which POCT was attempted, at least one valid POCT result was obtained and documented, and the result was available before the final conveyance decision.

Secondary Endpoints

- POCT attempted, defined as the proportion of intervention-cluster ambulance encounters in which blood sampling or POCT device use was initiated.
- Successful POCT measurement, defined as the proportion of POCT attempts yielding at least one valid reportable result.
- Decision-relevant POCT availability, defined as the proportion of POCT attempts where at least one valid result was documented before the final conveyance decision.
- Non-conveyance, defined as completion of the ambulance encounter without transport to hospital after on-scene ambulance assessment.
- Hospital admission within 24 hours among patients not conveyed at the index encounter.

- Short-stay hospitalization, defined as admission lasting less than 6 hours without advanced procedures or CT/MR imaging.
- Total hospital length of stay within 30 days.
- ICU admission within 30 days.
- All-cause mortality within 30 days.

3. Methods

Study period and setting

The study will be conducted from 1 June 2026 to 30 September 2027 within the Prehospital Emergency Medical Services of the Central Denmark Region.

Study Design

This is a prospective, matched, parallel, cluster-randomised trial conducted within a regional emergency medical services (EMS) system. A total of ten ambulances are included and randomly allocated in a 1:1 ratio to either an intervention strategy integrating point-of-care testing (POCT) into prehospital assessment or to standard care. Each ambulance constitutes a cluster and patient level allocation is determined by ambulance availability.

Prior to randomization, clusters are matched in pairs based on their non-conveyance rate during the preceding six months, overall case volume, geographic coverage, and ambulance type to ensure balance in baseline practice patterns and workload. Matched pairs are then randomized to intervention or control.

Practical Conduct

Sampling Framework

Five ambulances are allocated to the intervention arm and equipped with portable point-of-care testing (POCT) devices (iSTAT Alinity with CHEM8+ cartridges, QuickRead go C-reactive protein,

and HemoCue WBC DIFF), and five ambulances serve as control units providing standard care without access to POCT.

All eligible adult patients attended by these ambulances following an emergency call or GP-commissioned ambulance dispatch through the EMDC during the inclusion period may be enrolled. Ambulances are pair-matched prior to randomisation based on their non-conveyance rate during the preceding six months, overall case volume, geographic coverage, and ambulance type to ensure comparable baseline activity and patient mix between intervention groups. All participating ambulances operate within the same regional EMS system, follow identical dispatch procedures, and adhere to the same regional standard operating procedures for on-scene assessment, triage, telemedical consultation, and transport decisions.

Clinical management, triage, and transport decisions follow standard regional practice. Control ambulances do not have access to POCT during patient assessment. Apart from access to POCT devices and test results, all other aspects of patient care are identical between groups.

The sampling framework is designed to capture routine EMS patients initially considered for hospital conveyance and to evaluate whether rapid biochemical testing can be implemented with telemedical physician support before the final conveyance decision under real-world operational conditions.

Study Procedures

For each eligible patient in the intervention arm, the following procedures apply:

1. Identification of eligible patients following an emergency call or GP-commissioned ambulance dispatch through the EMDC and initial on-scene ambulance assessment.
2. Blood sampling using standard venous or capillary technique.
3. Immediate on-scene analysis using the iSTAT Alinity CHEM8+ cartridge, QuickRead go C-reactive protein, and HemoCue WBC DIFF as clinically indicated.

4. Documentation of clinical findings, POCT results, and conveyance decision in REDCap.
5. Telemedical consultation with a doctor (EMDC physician) to evaluate the POCT results
6. Continued standard EMS care, including transport or non-conveyance according to the final clinical decision.

In control ambulances, patients undergo identification, telemedical consultation (if indicated), documentation in REDCap, and standard EMS care without POCT.

No additional study-specific interventions beyond blood sampling in the intervention arm are introduced. All follow-up outcomes are obtained through routine registry linkage.

Intervention

The intervention consists of on-scene biochemical testing using portable point-of-care testing (POCT) devices:

- iSTAT Alinity CHEM8+ (sodium, potassium, chloride, calcium, urea, creatinine, glucose and total carbon dioxide)
- QuickRead go (C-reactive protein and hemoglobin)
- HemoCue WBC DIFF (white blood cell count differentiated) is used for leukocyte count.

These devices provide rapid biochemical results directly at the scene to support clinical assessment.

POCT may be performed in clinically stable patients who would otherwise be considered for hospital conveyance based on the initial on-scene ambulance assessment, including patients attended after GP-commissioned ambulance dispatch through the EMDC. The intervention therefore targets patients initially considered for hospital transport, in whom additional biochemical information may support reassessment of the conveyance decision.

Control clusters continue usual care without POCT. All data will be recorded prospectively.

Outcomes

Primary and secondary outcomes will be reported in the primary trial publication. Additional prespecified outcomes will be analyzed and reported in separate methodological, safety, and implementation-focused publications.

The primary outcome

The primary outcome is implementation of prehospital POCT, defined as the proportion of intervention-cluster ambulance encounters in which POCT was attempted, at least one valid POCT result was obtained and documented, and the result was available before the final conveyance decision.

Secondary outcomes:

Secondary outcomes will be compared between the randomized intervention and control clusters under the intention-to-treat principle where applicable. Outcomes include:

- Non-conveyance, defined as completion of the ambulance encounter without transport to hospital after on-scene ambulance assessment.
- Hospital admissions within 24 hours among non-conveyed patients.
- Short-stay hospitalization defined as admission lasting less than 6 hours without advanced procedures or CT/MR imaging.
- Total hospital length of stay.
- ICU admission rates.
- 30-day mortality.

Prespecified Substudy and Implementation Outcomes

The following additional outcomes are prespecified to support safety, operational, and methodological substudies.

Safety and Health Services Outcomes

- 30-day hospital admission rate, defined as any hospital admission occurring within 30 days after the index encounter.
- Emergency department (ED) visit or hospital admission within 72 hours after non-conveyance, defined as any ED encounter or hospital admission occurring within 72 hours of the index non-conveyance encounter, regardless of referral pathway (e.g., OOH-PC, EMS, general practitioner, or self-referred).
- OOH-PC (out-of-hour primary care) contact within 72 hours after non-conveyance, defined as any registered out-of-hours primary care contact within 72 hours of the index non-conveyance encounter.
- EMS recontact within 72 hours after non-conveyance, defined as any new emergency call resulting in ambulance dispatch within 72 hours of the index non-conveyance encounter.
- Days alive and out of hospital at 30 days, defined as the number of days within 30 days after the index encounter during which the patient is alive and not admitted to hospital.

Operational and Process Outcomes

- On-scene time, defined as time from ambulance arrival at scene to departure from scene, regardless of whether the patient is transported or not.
- POCT attempted, defined as the proportion of intervention-cluster ambulance encounters in which blood sampling or POCT device use was initiated.
- Successful POCT measurement, defined as the proportion of POCT attempts yielding at least one valid reportable result.
- Decision-relevant POCT availability, defined as the proportion of POCT attempts where at least one valid result was documented before the final conveyance decision.

Methodological Outcomes

- Estimated intra-cluster correlation coefficients (ICCs) for non-conveyance and selected key secondary outcomes (24-hour hospital admission among non-conveyed patients, 30-day

hospital admission, 30-day mortality, and short-stay hospitalization), to inform future matched cluster-randomized trials in comparable EMS settings.

- Observed design effects for non-conveyance and selected secondary clinical outcomes under the matched cluster-randomized design.
- Pair-matching performance metrics, including within-pair correlation of baseline non-conveyance rates and descriptive between-cluster variation prior to randomization.
- Data linkage and outcome completeness, including the proportion of patients successfully linked across data sources and the availability of key endpoint data.

Study Population

Clusters

The study will include 10 ambulance clusters, allocated 5 to the intervention arm and 5 to the control arm. Clusters will be matched prior to randomization based on their historical non-conveyance rate during the preceding six months, overall case volume, geographic coverage, and ambulance type to ensure balance in baseline practice patterns, workload, and patient mix between groups.

- Urban eastern region: 3 intervention and 3 control ambulances
- Rural western region: 2 intervention and 2 control ambulances

Patients

Inclusion Criteria:

- Adults aged ≥18 years
- Emergency calls or GP-commissioned ambulance dispatches through the EMDC resulting in attendance by a participating ambulance
- Initial on-scene assessments performed by the ambulance crew
- Patients initially considered for hospital conveyance based on clinical assessment

- Hemodynamically and clinically stable according to predefined operational stability criteria (including Glasgow Coma Scale, blood pressure, oxygen saturation, and heart rate), with final eligibility determined by the EMDC physician based on overall clinical assessment and the patient's known baseline status

Exclusion Criteria:

- Interfacility transfers or commissioned transports where the patient has been physically assessed by a general practitioner or another physician before ambulance arrival, and where the ambulance task is primarily transport based on that assessment
- Immediate need for emergency transport to hospital based on clinical assessment
- Persistent unstable vital signs outside predefined operational thresholds, except for known chronic baseline deviations (e.g., reduced oxygen saturation in patients with chronic obstructive pulmonary disease or chronic tachyarrhythmia in atrial fibrillation)
- Inability to obtain venous or capillary blood samples
- Prior participation in the study within 30 days (to ensure complete outcome follow-up)

Data sources and data collection

Only REDCap data will be entered prospectively. Prehospital operational and clinical data from the Prehospital Patient Record (PPJ) and Logis systems and in-hospital data from the electronical in-hospital patient records will be collected following formal approval from the Legal Office of the Central Denmark Region in accordance with applicable data protection regulations.

REDCap

Blood sampling variables will be entered into REDCap by ambulance personnel. REDCap will contain study-specific variables including POCT timing, test results, and unique study identification numbers.

Prehospital Patient Record (PPJ) and Logis (dispatch operational system) systems

The following prehospital variables may be collected:

• Time stamps (emergency call, dispatch, arrival on scene, departure from scene, hospital arrival where applicable)

• Dispatch reference code (Danish Index of Emergency Care)

• Ambulance cluster and EMS units involved

• Demographics (age and sex)

• Vital signs (GCS, oxygen saturation, blood pressure, pulse, and blood glucose where available)

• Telemedical consultation with EMDC physician (yes/no and time)

• Final prehospital decision (non-conveyance or hospital transport)

The regional electronic patient record (EPJ)

The following variables may be collected:

- Hospital admission within 24 hours following non-conveyance
- Total hospital length of stay
- ICU admission and ICU length of stay
- Discharge diagnoses (ICD-10)
- Mortality data (date of death)
- Historical ICD-10 data from a 10-year period to determine comorbidity

Data linkage and access control

Data linkage between REDCap, PPJ, Logis, and EPJ will be performed using the Danish civil registration number (CPR) within secure regional data environments in accordance with applicable data protection regulations.

Only authorized research personnel will have access to identifiable data. Access will be role-based and logged.

Data handling and storage

The project will be registered in the Central Denmark Region's internal registry of research projects and conducted in accordance with the General Data Protection Regulation (GDPR) and the Danish Data Protection Act.

The sponsor and principal investigator are responsible for ensuring that all data processing complies with applicable data protection legislation. Study data will be stored in REDCap on secure regional servers approved for research use. Access will be restricted to authorised study personnel.

Only data relevant to the research objectives will be collected and processed in accordance with data minimization principles. Identifiable data will be accessible only to authorized personnel involved in study conduct, data validation, or monitoring.

Data will be stored in accordance with Danish regulatory requirements and institutional policies. After the required retention period, data will be deleted or fully anonymized as appropriate.

Individual-level data will not be made publicly available. Aggregated and anonymized results may be shared upon reasonable request and subject to relevant approvals.

Statistics

All analyses will follow the intention-to-treat principle where applicable, with participants analyzed according to the allocation of their ambulance cluster regardless of whether POCT was performed. Analyses will primarily be descriptive and estimation-based, and effect estimates will be presented with 95% confidence intervals. Comparative analyses of clinical outcomes will account for ambulance-level clustering and the matched-pair design and will be considered exploratory.

Baseline characteristics will be summarized using descriptive statistics based on available data. Continuous variables will be presented as mean with standard deviation or median with interquartile range, as appropriate, and categorical variables as counts and percentages. No formal hypothesis testing of baseline differences will be performed.

The primary outcome, implementation of prehospital POCT, will be analyzed among intervention-cluster attended patient encounters within the study population. The outcome will be reported as the proportion of encounters in which POCT was attempted, at least one valid POCT result was obtained and documented, and the result was available before the final conveyance decision. This proportion will be presented with a 95% confidence interval. Each step in the implementation pathway will also be reported separately: POCT attempt, successful POCT measurement, documentation of a valid result, and availability of a valid result before the final conveyance decision.

Clinical outcomes, including non-conveyance, hospital admission within 24 hours among non-conveyed patients, short-stay hospitalization, total hospital length of stay, ICU admission, and 30-day mortality, will be compared between randomized intervention and control clusters as secondary and exploratory outcomes. Binary outcomes will be analyzed using linear regression models to estimate risk differences and Poisson regression models with robust variance estimation to estimate relative risks. Matched pair will be included as a fixed effect, and standard errors will be clustered at the ambulance level. Continuous outcomes will be analyzed using linear regression with matched-pair fixed effects and ambulance-level clustered standard errors, or summarized descriptively if model assumptions are not appropriate.

A per-protocol sensitivity analysis will be conducted among patients in intervention clusters in whom POCT was performed. These patients will be compared with propensity-score–matched controls from control clusters based on patient characteristics, vital signs, and presenting problem. The analysis will use the same modelling framework as the exploratory clinical outcome analyses, with estimation of risk differences and relative risks where appropriate. The per-protocol analysis will be interpreted as a sensitivity analysis to the randomized comparison of clinical outcomes.

The intra-cluster correlation coefficient will be estimated for non-conveyance and selected clinical outcomes where appropriate, to inform future cluster-randomized trials.

Sample Size and Power Considerations

The number of clusters is determined by the pre-specified organizational structure of the EMS system and the available POCT infrastructure. The study includes 10 ambulance clusters, with five allocated to the intervention arm and five to the control arm. We anticipate that each participating ambulance may attend up to approximately 250 patients within the study population during the study period, corresponding to approximately 1,250 attended patient encounters per arm.

These figures refer to patients attended by the participating ambulances within the study population and do not imply that all patients will be eligible for POCT. Some patients may be safely non-conveyed according to existing SOP without POCT, some will require hospital conveyance irrespective of POCT, and the proportion of patients in whom POCT is clinically relevant and attempted is unknown. Estimating this proportion is a central implementation outcome of the trial.

The trial is not powered to detect a definitive difference in non-conveyance or safety outcomes. Instead, the study is designed to estimate key implementation parameters, including the proportion of attended patient encounters in which POCT is attempted, the proportion of attempts yielding a valid result, decision-relevant POCT availability, documentation completeness, and outcome linkage. Clinical outcomes, including non-conveyance, will be reported as exploratory outcomes and used to inform the design and sample size of a future definitive effectiveness trial.

The primary analysis will focus on estimation of implementation outcomes. Exploratory comparisons of clinical outcomes between randomized clusters will account for the matched-pair cluster design where appropriate.

4. Ethics Approval

The study has been reviewed by the Central Denmark Region Committees on Health Research Ethics (case no. 1-10-72-8-26), which determined that the study does not require approval under Danish legislation. Registry-based follow-up will be conducted under relevant regional legal and data protection approvals.

An English description of the ethical assessment will be provided in the ClinicalTrials.gov registration.

Limitations/Discussion

Because POCT use must be evaluated by the EMDC physician, the intervention inevitably increases the frequency of telemedical consultations. Thus, any observed differences between groups reflect the combined effect of POCT and increased physician involvement. The study cannot isolate the independent effect of POCT alone, and findings should be interpreted as the impact of this integrated care model.

References

1. Andrew E, Nehme Z, Cameron P, Smith K. Drivers of Increasing Emergency Ambulance Demand. Prehosp Emerg Care. 2020;24(3):385.

2. Lowthian JA, Cameron PA, Stoelwinder JU, Curtis A, Currell A, Cooke MW, et al. Increasing utilisation of emergency ambulances. Aust Health Rev Publ Aust Hosp Assoc. 2011 Feb;35(1):63–9.

3. Lowthian JA, Curtis AJ, Cameron PA, Stoelwinder JU, Cooke MW, McNeil JJ. Systematic review of trends in emergency department attendances: an Australian perspective. Emerg Med J EMJ. 2011 May;28(5):373–7.

4. Christensen EF, Bendtsen MD, Larsen TM, Jensen FB, Lindskou TA, Holdgaard HO, et al. Trends in diagnostic patterns and mortality in emergency ambulance service patients in 2007-2014: a population-based cohort study from the North Denmark Region. BMJ Open. 2017 Aug 21;7(8):e014508.

5. Booker MJ, Shaw ARG, Purdy S. Why do patients with ‘primary care sensitive’ problems access ambulance services? A systematic mapping review of the literature. BMJ Open. 2015 May 19;5(5):e007726.

6. Paulin J, Kurola J, Salanterä S, Moen H, Guragain N, Koivisto M, et al. Changing role of EMS -analyses of non-conveyed and conveyed patients in Finland. Scand J Trauma Resusc Emerg Med. 2020 May 29;28(1):45.

7. Todd VF, Swain A, Howie G, Tunnage B, Smith T, Dicker B. Factors Associated with Emergency Medical Service Reattendance in Low Acuity Patients Not Transported by Ambulance. Prehosp Emerg Care. 2022;26(1):66–77.

8. Hoikka M, Silfvast T, Ala-Kokko TI. A high proportion of prehospital emergency patients are not transported by ambulance: a retrospective cohort study in Northern Finland. Acta Anaesthesiol Scand. 2017 May;61(5):549–56.

9. Fisher JD, Freeman K, Clarke A, Spurgeon P, Smyth M, Perkins GD, et al. Patient safety in ambulance services: a scoping review [Internet]. Southampton (UK): NIHR Journals Library; 2015 [cited 2025 Dec 4]. (Health Services and Delivery Research). Available from: http://www.ncbi.nlm.nih.gov/books/NBK294028/

10. Malm F, Elfström A, Ohlsson-Nevo E, Höglund E. Time consumption for non-conveyed patients within emergency medical services (EMS): A one-year prospective descriptive and comparative study in a region of Sweden. PloS One. 2021;16(5):e0251686.

11. Ebben RHA, Vloet LCM, Speijers RF, Tönjes NW, Loef J, Pelgrim T, et al. A patient-safety and professional perspective on non-conveyance in ambulance care: a systematic review. Scand J Trauma Resusc Emerg Med. 2017 Jul 17;25(1):71.

12. Møller FA, Gude MF, Nielsen RØ, Gehrt TB. Patient safety in non-conveyance within prehospital emergency medical services: a register-based study. Intern Emerg Med. 2025 May 22;