Study administrative information

Project name	Prehospital Point-of-Care High-Sensitivity Troponin I for Rule-Out of Acute Myocardial Infarction in Suspected Non–ST-Segment Elevation Acute Coronary Syndrome: A Pilot Study
Project Acronym	Pre-POCT Troponin Pilot Study
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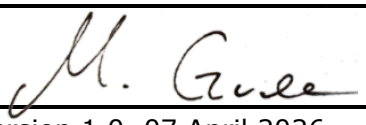
Sponsor-Investigator signature	
Protocol version and date	Version 1.0, 07 April 2026
Study coordinator	Arne Sylvester Rønde Jensen, Paramedic

Background, purpose, outcomes and hypothesis

Patients presenting with cardiac-related symptoms, particularly chest pain, represent a substantial proportion of contacts to emergency medical services (EMS). Danish studies have shown that chest pain accounts for approximately 10–11% of all ambulance runs.[1–3] However, despite the high prevalence of suspected cardiac symptoms, only a minority of these patients are ultimately diagnosed with acute coronary syndrome (ACS). Previous research from Denmark has demonstrated that approximately one in ten patients transported to hospital with chest pain suggestive of cardiac origin receive a final diagnosis of ACS.[3,4] This reflects a high-volume, low-event-rate population in which the majority of patients do not have acute coronary disease and the short-term risk of major adverse cardiac events (MACE) is correspondingly low.

Consequently, a large proportion of patients undergo hospital transport and diagnostic evaluation despite a low probability of ACS, highlighting the potential value of early risk stratification in the prehospital setting to improve triage and reduce unnecessary transport.

Several clinical tools and diagnostic strategies have been developed to support early risk stratification in this patient group. The HEART score (History, ECG, Age, Risk factors, and Troponin) is a well-validated clinical risk stratification tool widely used in emergency departments for patients with suspected ACS.[5] Modified versions incorporating point-of-care troponin testing have also been evaluated in the prehospital setting to support risk stratification by ambulance clinicians.[6]

In Denmark, point-of-care cardiac troponin measurements have been implemented in the prehospital setting using portable analyzers such as the Roche Cobas h232 system. However, these assays measure conventional troponin and have relatively high detection thresholds, typically around 40-50 ng/L, which limits their ability to detect low troponin concentrations compared with hospital-based high-sensitivity assays.[7]

High-sensitivity cardiac troponin (hs-cTn) has been extensively investigated in the emergency department (ED) setting, where it forms the cornerstone of accelerated diagnostic pathways for patients presenting with suspected ACS.[8] Serial measurements of hs-cTn enable rapid and safe rule-out or rule-in of myocardial infarction, and these strategies are widely implemented in clinical guidelines.[9,10]

In contrast, the use of hs-cTn in the prehospital environment remains comparatively underexplored. A randomized trial using prehospital point-of-care troponin demonstrated that an early rule-out strategy may reduce hospital length of stay and resource use; however, the study relied on conventional troponin assays and was not designed to support prehospital triage decisions such as non-conveyance.[5] Observational studies of prehospital high-sensitivity troponin testing have further suggested potential for early risk stratification, but the available evidence remains limited and heterogeneous.[11] Consequently, the clinical utility of hs-cTn for guiding prehospital decision-making has not yet been established.

The present study therefore aims to evaluate the feasibility and diagnostic performance of prehospital point-of-care (POCT) measurement of high-sensitivity cardiac troponin I (hs-TnI) in patients with suspected ACS, in comparison with standard in-hospital laboratory-based high-sensitivity troponin testing. By extending the use of high-sensitivity biomarkers to the prehospital setting through POCT, the study seeks to generate evidence to inform future risk stratification strategies and potential triage pathways.

In addition, the study will explore the relationship between time from symptom onset to biomarker measurement and hs-TnI concentrations, with the aim of identifying patient

subgroups with differing risk profiles. This includes patients with low hs-TnI concentrations consistent with low risk of acute coronary syndrome and major adverse cardiac events, patients with intermediate hs-TnI concentrations who may represent a subgroup in which repeat prehospital measurement could be considered in future risk stratification strategies, and patients with elevated hs-TnI concentrations associated with higher risk. These analyses are exploratory and are not used to guide clinical decision-making within the present study.

If prehospital hs-TnI measurement can reliably identify low-risk patients, this may support safer clinical decision-making regarding hospital transport and reduce unnecessary admissions, thereby improving patient flow and resource utilization.

Hypothesis

The primary hypothesis of the study is that patients presenting with cardiac-related symptoms who have low prehospital hs-TnI concentrations have a low risk of acute coronary syndrome and major adverse cardiac events.

It is further hypothesized that prehospital hs-TnI measurements, in combination with time from symptom onset to measurement, may enable identification of clinically relevant risk strata. These include patients with low hs-TnI concentrations consistent with low risk of acute coronary syndrome and major adverse cardiac events, patients with intermediate hs-TnI concentrations who may represent a group in which repeat prehospital measurement could be considered in future strategies, and patients with elevated hs-TnI concentrations associated with a higher risk of acute coronary syndrome and major adverse cardiac events.

These stratifications are exploratory and are not used to guide clinical decision-making within the present study, but may inform future prehospital risk stratification and triage strategies, including potential non-conveyance pathways.

Methods

Design and setting

Prospective observational diagnostic accuracy and feasibility study. The study does not include randomization or a control group, as the purpose is to evaluate feasibility and diagnostic performance rather than clinical effectiveness.

Diagnostic performance of prehospital high-sensitivity cardiac troponin I (hs-TnI) will be evaluated for the identification of acute coronary syndrome and prediction of major adverse cardiac events. Performance will be reported using sensitivity, specificity, positive and negative predictive values, likelihood ratios, and area under the receiver operating characteristic curve (AUC-ROC) with 95% confidence intervals. The reference standard will be the final hospital diagnosis of acute coronary syndrome based on standard clinical

evaluation, including serial cardiac troponin measurements, electrocardiography, and other diagnostic procedures as clinically indicated.

Sampling framework

Convenience sampling will be conducted in six ambulances in the Central Denmark Region equipped with i-STAT devices and staffed by personnel trained in point-of-care testing (POCT) procedures. All patients presenting with symptoms suggestive of acute coronary syndrome (ACS), including chest pain or other cardiac-related symptoms, who are managed by these ambulances during the inclusion period may be considered for inclusion.

Five of the study ambulances are intervention units in an ongoing cluster-randomized POCT trial using a separate set of study samples. One additional ambulance unit in Silkeborg is not part of that trial but is equipped with the i-STAT platform and trained in identical POCT procedures and is included to increase recruitment capacity. All study ambulances operate under the same regional standard operating procedures for assessment, triage, and transport of patients with suspected ACS.

Eligibility criteria

Patients are eligible for inclusion if they meet all of the following criteria:

- Age ≥18 years
- Assessed by one of the participating study ambulances
- Presentation with symptoms suggestive of ACS, including chest pain or other cardiac-related symptoms
- Managed with planned transport to hospital for further evaluation

Patients will be excluded if any of the following criteria are present:

- ST-segment elevation on prehospital ECG
- Clinical condition requiring immediate life-saving intervention precluding study procedures
- Interhospital transport
- Prior inclusion in the study within 30 days

Study procedures

One prehospital blood sample (<0.5 mL) will be obtained during routine EMS assessment.

Study procedures include:

1. **Identification of eligible patients**
   EMS personnel identify patients presenting with symptoms suggestive of ACS according to predefined study inclusion and exclusion criteria.

2. **Blood sampling and analysis**
   A venous blood sample is obtained and analyzed using the i-STAT point-of-care platform according to manufacturer instructions and local POCT procedures.
3. **REDCap entry**
   Troponin measurements and relevant clinical data are entered into REDCap by EMS personnel.
4. **Standard EMS care continues**
   Patient assessment, treatment, triage, consultation with medical control, and transport decisions proceed according to standard regional EMS protocols and are not influenced by study participation.

Hospital diagnostics and reference standard

All patients will receive in-hospital diagnostic evaluation and clinical management according to usual clinical indications, independent of study participation. Diagnostic evaluation may include serial cardiac troponin measurements, electrocardiography, coronary imaging, and other investigations as clinically indicated.

Hospital records will be used to determine final diagnoses and clinical outcomes. The reference standard for acute coronary syndrome is the final hospital diagnosis based on standard clinical evaluation, including serial cardiac troponin measurements, electrocardiography, and other diagnostic procedures as clinically indicated.

Patients discharged without a diagnosis of acute coronary syndrome and without subsequent occurrence of major adverse cardiac events within 30 days will be classified as not having acute coronary syndrome for the purpose of diagnostic accuracy analyses.

Outcomes

Primary outcome

The primary outcome is the occurrence of major adverse cardiac events (MACE) within 30 days of the index EMS contact. MACE includes one or more of the following events:

- Acute myocardial infarction
- Coronary revascularization
- Cardiovascular death

Secondary outcomes

- Final diagnosis of acute coronary syndrome at 24 hours
- All-cause mortality within 30 days
- Coronary revascularization within 30 days
- Diagnostic performance of prehospital high-sensitivity cardiac troponin I (hs-TnI) for identification of acute coronary syndrome at 24 hours

- Diagnostic performance of prehospital hs-TnI for prediction of major adverse cardiac events within 30 days

Other pre-specified outcomes

Additional outcomes related to feasibility and analytical performance include:

- Proportion of eligible patients with successful prehospital blood sampling
- Proportion of valid hs-TnI measurements
- Time from first EMS patient contact to availability of hs-TnI result
- Agreement between prehospital and in-hospital hs-TnI measurements in a predefined subset of patients admitted directly to the Department of Cardiology, where prehospital blood samples are handed over for in-hospital laboratory analysis
- Exploratory stratification of patients will be performed according to prehospital hs-TnI concentrations in relation to time from symptom onset. Patients will be categorized into groups with low hs-TnI concentrations associated with low risk of acute coronary syndrome and major adverse cardiac events, intermediate hs-TnI concentrations, and elevated hs-TnI concentrations associated with higher risk. These analyses are descriptive and exploratory and are not used to guide clinical management. The identified strata are intended to inform potential future risk stratification strategies, including repeat prehospital assessment and triage pathways.

Blinding and clinical decision-making

Troponin results obtained from the i-STAT device are visible on the device and entered into REDCap by EMS personnel at the time of sampling. Clinical personnel are therefore not formally blinded to numeric troponin values.

However, the biomarker results are not permitted to be used for clinical decision-making. EMS personnel receive no training, interpretation guidance, reference framework, or clinical cut-off values for hs-TnI. Biomarker-based decision thresholds are not established for prehospital use within the Central Denmark Region, and no EMS protocols incorporate troponin-based decision-making.

Consequently, the numeric results are not used to guide prehospital management and cannot systematically influence clinical decision-making. Patients are not informed of the biomarker results during the prehospital or in-hospital phase and are therefore blinded to study test results.

Deviations from standard care

There are no deviations from standard clinical care. Biomarker sampling is performed in parallel with routine EMS assessment and does not change triage, treatment, consultation with medical control, or transport decisions.

Statistical considerations

Statistical methods

This is a prospective diagnostic accuracy and feasibility pilot study. Statistical analyses are primarily descriptive and exploratory and aim to quantify diagnostic performance, clinical outcomes, feasibility parameters, and exploratory risk stratification, as well as to provide variance estimates for planning future interventional studies.

Primary outcome analysis

The occurrence of major adverse cardiac events (MACE) within 30 days will be summarized as a proportion with corresponding 95% confidence intervals.

Secondary outcome analyses

Final diagnosis of acute coronary syndrome at 24 hours, all-cause 30-day mortality, and coronary revascularization within 30 days will be summarized as proportions with corresponding 95% confidence intervals.

Diagnostic performance of prehospital high-sensitivity cardiac troponin I (hs-TnI) will be evaluated for:

- identification of acute coronary syndrome at 24 hours
- prediction of major adverse cardiac events within 30 days

The following measures will be calculated:

- Sensitivity
- Specificity
- Positive predictive value (PPV)
- Negative predictive value (NPV)
- Positive likelihood ratio (LR+)
- Negative likelihood ratio (LR−)
- Area under the receiver operating characteristic curve (AUC-ROC)

Analyses will be performed using hs-TnI both as a continuous variable and across exploratory threshold values.

All point estimates will be reported with 95% confidence intervals. Confidence intervals for proportions (e.g., sensitivity, specificity, PPV, NPV) will be calculated using exact (Clopper–Pearson) or Wilson methods as appropriate. Confidence intervals for likelihood ratios will be derived using standard log-transformation methods.

Receiver operating characteristic (ROC) curves will be constructed for hs-TnI.

Other pre-specified outcome analyses

Feasibility outcomes, including successful prehospital blood sampling and valid hs-TnI measurements, will be summarized as proportions with corresponding 95% confidence intervals. Time from first EMS contact to availability of hs-TnI results will be summarized using medians and interquartile ranges.

Agreement between prehospital POCT hs-TnI measurements and in-hospital hs-TnI measurements will be assessed in a predefined subset of patients using complementary statistical methods. Bland–Altman analysis will be used to evaluate agreement, correlation analyses to describe association, and Passing–Bablok regression to assess systematic and proportional differences between methods.

Exploratory analyses

Exploratory analyses will evaluate hs-TnI concentrations in relation to time from symptom onset and clinical outcomes. Patients will be categorized into strata reflecting low, intermediate, and higher risk profiles, and the distribution of outcomes across these strata will be described.

No adjustment for multiple comparisons will be performed due to the exploratory nature of the study.

Sample size consideration

This study is designed as a diagnostic accuracy and feasibility pilot study and is not powered as a confirmatory trial. Accordingly, no formal sample size calculation has been performed. The planned sample size of approximately 500 participants is based on feasibility considerations and is considered sufficient to provide preliminary estimates of diagnostic performance, clinical outcomes, and feasibility parameters, as well as variance estimates to inform the design and power calculations of future interventional studies.

Handling of missing data

The extent and pattern of missing data will be described. Diagnostic accuracy analyses will be performed using available-case analyses. No imputation of biomarker values is planned due to the pilot nature of the study.

Data sources and management

Relevant information will be obtained from prospectively collected on-scene study data and from prehospital and hospital records.

Prospectively collected on-scene study data (REDCap)

The following data are recorded prehospitally in REDCap by trained EMS or research personnel:

- Civil registration number (CPR) for secure data linkage
- Date and time of inclusion
- Symptom onset time

Biomarker-related data:

- i-STAT Alinity hs-TnI cartridge
- Quantitative result
- Cartridge ID
- Time of blood sampling and analysis
- Error codes, if applicable

REDCap is a secure, regionally approved research database with audit trails and role-based access control.

Prehospital record data (PPJ and Logis)

Relevant information from the Prehospital Patient Record (PPJ) and Logis systems will be obtained after study completion following approval from the Legal Office, Central Denmark Region, in accordance with Danish legislation. These data will be merged with REDCap data using CPR-based linkage within secure regional data environments.

The following variables may be collected:

- Time stamps (emergency call, dispatch, arrival, departure, hospital arrival)
- Dispatch reference code (Danish Index of Emergency Care)
- EMS units involved
- Treatments administered (e.g., paracetamol, NSAIDs, opioids) including time and dose
- Demographics (age and sex)
- Vital signs (GCS, oxygen saturation, blood pressure, blood glucose, pulse)
- Triage decisions (non-conveyance, hospital admission, referral to general practitioner or out-of-hours primary care)

Hospital data (EPJ)

Relevant hospital data will be obtained after study completion from the regional electronic health record (EPJ) following approval from the Legal Office, Central Denmark Region, and merged with study data using CPR-based linkage.

The following variables may be collected:

- Results of in-hospital cardiac investigations, including serial cardiac troponin measurements and electrocardiography (ECG)
- Coronary imaging and procedures, including coronary angiography and coronary revascularization (PCI or CABG)
- ICU admission and length of stay
- Hospital length of stay, including the first hospital admission and any subsequent interhospital transfers
- Discharge diagnoses (ICD-10)
- Comorbidity based on ICD-10 diagnoses from hospital contacts within the previous 10 years
- Mortality data (date of death)

These data will be collected to characterize the study population, determine final clinical diagnoses, describe clinical outcomes, and evaluate the diagnostic performance and clinical relevance of prehospital high-sensitivity cardiac troponin I (hs-TnI) measurements in patients with suspected acute coronary syndrome.

Timeframes for record access

REDCap data will be completed at the index event. Prehospital and in-hospital patient record data will be applied for at the Legal Office, Central Denmark Region, in accordance with Danish legislation after completion of the study and inclusion period.

Data linkage and access control

Data linkage between REDCap, prehospital records, and hospital records is performed using CPR within secure regional data environments in accordance with applicable data protection regulations. CPR numbers are stored separately from analysis datasets and replaced by unique study identification numbers prior to analysis. Only authorized research personnel have access to identifiable data.

Data storage and protection

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 the principal investigator are responsible for ensuring that all data processing complies with applicable data protection legislation.

A limited dataset is recorded prospectively in REDCap at the index event, including biomarker data and key patient identifiers required for data linkage. REDCap is hosted on secure regional servers approved for research use, with role-based access control and full audit trails.

Prehospital (PPJ and Logis) and in-hospital (EPJ) data are not entered into REDCap during the inclusion phase. These data will be obtained after study completion through application to

the Legal Office, Central Denmark Region, in accordance with Danish legislation. Following approval, data will be linked to REDCap data using CPR within secure regional data environments.

Civil registration numbers (CPR) are used solely for secure data linkage between data sources. CPR numbers are stored separately from analysis datasets and replaced by unique study identification numbers prior to analysis.

Only data relevant to the research objectives are collected and processed, in accordance with data minimization principles. Access to identifiable data is restricted to authorized research personnel who require access for study conduct, data linkage, or validation.

Data will be stored for the period required by Danish regulations and institutional policies for health research documentation. After this period, data will be deleted or fully anonymized in accordance with applicable rules.

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

Transfer of personal data abroad

No personal data will be transferred outside Denmark as part of this project. All data processing and storage take place within secure regional systems in Denmark.

Should any future need for international data sharing arise, this will only occur after appropriate approvals from relevant authorities and in full compliance with GDPR Chapter V and applicable Danish legislation.

Study population and feasibility context

Study participants

Approximately 500 participants are expected to be included in this study.

Inclusion criteria

- Age ≥18 years
- Managed by one of the study ambulances equipped for POCT sampling
- Presentation with symptoms suggestive of acute coronary syndrome
- Managed with planned transport to hospital for further evaluation

Exclusion criteria

- ST-segment elevation on prehospital electrocardiogram
- Clinical condition requiring immediate life-saving intervention precluding study procedures
- Prior participation in the study within 30 days
- Interhospital transport

Study period

The planned inclusion period is approximately 12–24 months. Exact start and end dates may be adjusted depending on logistical and operational considerations.

Ethics and safety

Risks and burden

The study involves minimal risk.

The only research-specific procedure is collection of a few drops of blood (<0.5 mL) from intravenous access placed as part of routine EMS care. No additional venipuncture is required.

Study participation does not alter clinical assessment, triage, treatment, or transport decisions. No radiation exposure is introduced by the study. No delays in clinical care are expected.

The study is therefore considered to involve minimal risk and minimal burden.

Economy

The study is investigator-initiated by Martin F. Gude, MD, PhD, at the Department of Research and Development, Prehospital Emergency Medical Services, Central Denmark Region.

There is no commercial sponsorship or industry funding. A research-year medical student is funded internally by the Prehospital Emergency Medical Services.

POCT equipment has been financed through a regional funding allocation (approximately 309,000 DKK) to support patient-near diagnostics. Consumables are covered by departmental operational budgets.

Abbott Point of Care has no role in the study and provides no funding or material support.

The investigators have no financial conflicts of interest.

Participant compensation

Participants do not receive financial compensation or other material benefits. Participation does not incur additional expenses, and no reimbursement for transport or lost income is provided, as all procedures are conducted as part of routine prehospital care.

Recruitment

Potential participants are identified by EMS personnel in participating ambulances when attending patients with suspected acute coronary syndrome who meet the study eligibility criteria.

Recruitment takes place exclusively during routine EMS missions and is based on real-time identification of eligible patients. No advertisements, registries, or public recruitment methods are used.

Publication of results

Study results will be published in peer-reviewed journals and may be presented at scientific conferences, regardless of outcome. Publication will follow principles of scientific transparency and responsible research conduct. Authorship will follow the Vancouver guidelines. No external party has influence on publication decisions. Results may also be reported in relevant public research registries.

Scientific-ethical justification

The study evaluates prehospital measurement of high-sensitivity cardiac troponin I (hs-TnI) in patients with suspected acute coronary syndrome, addressing a relevant knowledge gap in prehospital risk stratification. The additional burden is minimal, as blood sampling is performed through existing intravenous access and does not affect clinical management. Risks are negligible and limited to minor discomfort.

Patients with suspected cardiac symptoms constitute a large proportion of EMS contacts, with a low rate of confirmed ACS. Improved early risk stratification may support more appropriate triage and more efficient use of healthcare resources. The study is therefore considered scientifically and ethically justified.

Compensation scheme

The study does not fall under the Danish Patient Compensation Act, as it is conducted within the framework of routine clinical care and does not involve an interventional research procedure. No study-specific compensation scheme or insurance is established.

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