The impact of prehospital blood sampling on the emergency department process of patients with chest pain, a pragmatic non-randomized controlled trial

Submission date	Recruitment status No longer recruiting	Prospectively registered		
05/01/2022		☐ Protocol		
Registration date 09/01/2022	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 13/02/2024	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Current plain English summary as of 03/05/2022:

Background and study aims

In patients with acute chest pain who arrive at the emergency department (ED) by ambulance, venous access is frequently established prehospital, and could be utilized to sample blood. Prehospital blood sampling may save time in the diagnostic process, which may ultimately improve clinical outcome. In our study, we assessed whether prehospital blood draw is independently associated with shorter blood sample arrival times at the laboratory, shorter troponin turnaround times, and shorter ED length of stay (LOS) in patients with chest pain without abnormalities at their ECG, arriving at the ED by ambulance for cardiology. Our hypothesis was that prehospital blood draw shortens all three time intervals, potentially expediting care for chest pain patients without abnormalities at their ECG.

Who can participate?

All adult patients who were transported to the ED by ambulance with chest pain and no abnormalities at their prehospital ECG.

What does the study involve?

We assessed the three time intervals in patients who were transported to the ED with chest pain without abnormalities at their prehospital electrocardiogram. Time intervals were compared between cases, in whom prehospital blood draw was performed, and controls, in which blood drawn was performed at the ED. We assessed the association of prehospital blood draw with blood sample arrival times, troponin turnaround times, and ED LOS using multivariate analyses. We also compared blood sample mix-ups and blood sample quality (number of hemolysis and insufficient blood) between cases and controls.

What are the possible benefits and risks of participating?

There are no risks. Possible benefits were shorter waiting times before results of blood are available, and shorter length of stay at the emergency department.

Where is the study run from?

The study ran from an inner-city hospital in the Hague, the Netherlands and the Emergency Medical Service in the Hague.

When is the study starting and how long is it expected to run for? January 2019 to February 2020.

Who is funding the study?

This study was funded by a grant from the Research Fund of Haaglanden Medical Centre (Netherlands). The funding source had no involvement in the study design, the collection, analysis and interpretation of the data, nor in the writing of the report and in the decision to submit the article for publication.

Who is the main contact?

Christien van der Linden, PhD, c.van.der.linden@haaglandenmc.nl

Previous plain English summary:

Background and study aims

In patients with acute chest pain who arrive at the emergency department (ED) by ambulance, venous access is frequently established prehospital, and could be utilized to sample blood. Prehospital blood sampling may save time in the diagnostic process, which may ultimately improve clinical outcome. In our study, we assessed whether prehospital blood draw is independently associated with shorter blood sample arrival times at the laboratory, shorter troponin turnaround times, and shorter ED length of stay (LOS) in patients with chest pain without ST-segment elevation myocardial infarction (STEMI), arriving at the ED by ambulance. Our hypothesis was that prehospital blood draw shortens all three time intervals, potentially expediting care for chest pain patients without STEMI.

Who can participate?

All adult patients who were transported to the ED by ambulance with chest pain and no ST-elevation at their prehospital ECG.

What does the study involve?

We assessed the three time intervals in patients who were transported to the ED with chest pain without STEMI at their prehospital electrocardiogram. Time intervals were compared between cases, in whom prehospital blood draw was performed, and controls, in which blood drawn was performed at the ED. We assessed the association of prehospital blood draw with blood sample arrival times, troponin turnaround times, and ED LOS using multivariate analyses.

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Who is the main contact? Christien van der Linden, PhD, c.van.der.linden@haaglandenmc.nl

Contact information

Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Z19-024

Study information

Scientific Title

In patients who are transported to the emergency department with chest pain and no abnormalities at their prehospital ECG, what are the blood sample arrival times, troponin turnaround times, and length of stay of patients in whom prehospital blood draw is performed compared with controls in whom blood draw is performed at the emergency department? BCLOSED (Blooddraw Chestpain patients, impact on Length Of Stay at the Emergency Department)

Acronym

B-CLOSED

Study objectives

Current study hypothesis:

Prehospital blood draw shortens all three time intervals, potentially expediting care for chest pain patients with no abnormalities at their ECG.

Previous study hypothesis:

Prehospital blood draw shortens all three time intervals, potentially expediting care for chest pain patients without STEMI.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/08/2019, Regional medical research committee Southwest Holland (METC-LDD, Albinusdreef 2, Postbus 9600, 2300 RC Leiden, Netherlands; +31(0)71-5263241; metc-ldd@lumc. nl), ref: 19-024, METC LDD

Study design

Pragmatic non-randomized controlled trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Patients with chest pain without abnormalities at their ECG, arriving at the ED by ambulance for cardiology

Interventions

Current interventions as of 03/05/2022:

We conducted a pragmatic non-randomized controlled trial, comparing chest pain patients who underwent prehospital blood sampling with chest pain patients who were also brought in by ambulance, but in whom blood was drawn in the ED. The single-centre study took place at an ED in an inner-city teaching hospital and an EMS in The Hague, the Netherlands over a 5-month period (October 1, 2019 to February 29, 2020). Patients were eligible for inclusion in our study when they had chest pain as chief complaint, had no abnormalities at their prehospital ECG, were 18 years or older, and were brought to the ED for cardiology with ambulance urgency level A2.

Upon arrival at the ED, patients are triaged according to the Manchester Triage System (MTS). Only the patients who were assigned to triage level 2 (very urgent) according to the MTS were included in the study. Patients who died at the ED, patients who left the ED against medical advice, and patients who were transferred to another facility were excluded from the study. Of patients with more than one ED visit during the study period, only the first ED visit was included.

Participating ambulance nurses approached the patients who fulfilled the inclusion criteria for informed consent, while the patient was lying in the ambulance. After the patients' consent, blood sampling was performed by the ambulance nurse. The participating EMS nurses performed blood draws only in combination with the insertion of a PIVC. No changes were made in the procedure for obtaining blood specimen in the ED: the blood sample was obtained through venepuncture or by drawing blood through a previously inserted PIVC (usual practice). The laboratory procedures for processing blood samples remained unchanged.

Previous interventions:

We conducted a non-randomized controlled trial, comparing chest pain patients who underwent prehospital blood sampling with chest pain patients who were also brought in by ambulance, but in whom blood was drawn in the ED. The single-centre study took place at an ED in an inner-city teaching hospital and an EMS in The Hague, the Netherlands over a 5-month period (October 1, 2019 to February 29, 2020). Patients were eligible for inclusion in our study when they had chest pain as chief complaint, had no ST-segment elevation at their prehospital ECG, were 18 years or older, and were brought to the ED with ambulance urgency level A2.

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Intervention Type

Procedure/Surgery

Primary outcome measure

All measured retrospectively:

- 1. Patient demographics: age and gender measured using hospital information system, through query
- 2. Patients' medical history and risk factors for cardiac ischemic events (smoking history, diabetes mellitus, hypertension, dyslipidemia, prior cardiovascular disease, family history coronary disease) measured using reviewing patient notes in the hospital information system
- 3. Arrival time measured using hospital information system, through query
- 4. Troponin values measured using reviewing patient notes in the hospital information system
- 5. Whether or not the patient underwent radiology tests measured using hospital information

system, through query

- 6. Disposition measured using hospital information system, through query
- 7. Time intervals: Blood sample arrival times at the laboratory were defined as the duration between patient arrival at the ED and blood sample arrival at the laboratory. Troponin turnaround time was defined as time between patient arrival at the ED and the availability of the troponin result in the hospital information system. ED LOS was defined as the time between the patient's presentation at the ED and the time the patient left the ED to be admitted or discharged home measured using measured using hospital information system, through query 8. Whether the patient arrived during extreme busyness at the ED was measured with the NEDOCS, the National ED OverCrowding Score, a multidimensional scale to measure patient volume and hospital throughput measured using hospital information system, through query

Secondary outcome measures

Current secondary outcome measures as of 03/05/2022:

- 1. Number of blood sample mix-ups
- 2. Blood sample quality (hemolysis and insufficient blood)

Previous secondary outcome measures: There are no secondary outcome measures

Overall study start date

01/01/2019

Completion date

29/02/2020

Eligibility

Key inclusion criteria

Current inclusion criteria as of 03/05/2022:

- 1. Patients with chest pain and no abnormalities at their ECG
- 2. Adult (18 years and older)
- 3. Transported by ambulance
- 4. Triage level 2 (orange)
- 5. Assessment by cardiology

Previous inclusion criteria:

- 1. Patients with chest pain and no ST-elevation at their ECG
- 2. Adult (18 years and older)
- 3. Transported by ambulance
- 4. Triage level 2 (orange)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

196

Total final enrolment

506

Key exclusion criteria

- 1. Age < 18 years
- 2. Not fulfilling inclusion criteria

Date of first enrolment

01/10/2019

Date of final enrolment

29/02/2020

Locations

Countries of recruitment

Netherlands

Study participating centre Haaglanden Medical Centre

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Sponsor information

Organisation

Haaglanden Medical Centre

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Sponsor type

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Haaglanden Medical Centre

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/03/2022

Individual participant data (IPD) sharing plan

The dataset used and analysed during the current study is available from the corresponding author on reasonable request. c.van.der.linden@haaglandenmc.nl

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article			13/02/2024	Yes	No