Prediction of Sepsis in the Emergency Room with Pulse Wave applied Machine Learning

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON51532

Source
ToetsingOnline

Brief title
RADAR study

Condition

- Other condition

Synonym
bloedvergifiting, sepsis

Health condition

spoedeisende hulp

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Edwards Lifesciences

Intervention

Keyword: Deterioration, Emergency Room, Machine Learning, Sepsis

Outcome measures

Primary outcome

The primary aim of this study is to predict deterioration in patients admitted to the ED. More specifically, we aim to predict sepsis, septic shock and cardiovascular instability based on the hemodynamic profile of the patient. Therefore, we will collect the continuous noninvasive arterial pressure waveform signals with the ClearSight (CS) finger cuff. In combination with the electronic medical record (EMR) data of the patient, we will develop a machine learning framework for the predictive tasks.

Secondary outcome

The secondary aim of this study is to determine the optimal patient-specific therapeutic pathway and thereby aiming to determine fluid responsiveness of the patient. Furthermore, within the machine learning framework, we will investigate whether hospitalization (ICU or general ward) of ED patients can be predicted.

Study description

Background summary

Unidentified deterioration in patients admitted to the emergency department

(ED) results in an increased mortality rate. Sepsis, septic shock and cardiovascular instability are frequent problems in these patients. (Abnormal) changes in clinical manifestation of these patients often precede the deterioration itself. Failure to recognize these changes may result in inappropriate treatment and increased mortality. Therefore, early identification of deterioration of the patient may contribute to improve outcome of deteriorating patients.
The hemodynamic profile of these patients provide information of the state of the patient and potentially holds predictive information for the prediction of deterioration. Therefore, in this research, we will conduct a prospective data collection study at the ED. We will collect the continuous noninvasive arterial pressure waveform signals with the ClearSight (CS) finger cuff. With these data, a machine learning framework will be developed to predict sepsis, septic shock and cardiovascular instability in patients admitted to the ED.

Study objective

The primary aim of this study is early identification of sepsis (and septic shock) and cardiovascular instability, based on the hemodynamic profile of ED patients. Continuous noninvasive arterial pressure waveform signals will be collected with the ClearSight (CS) finger cuff. In combination with clinical data from patients* electronic medical record (EMR), a machine learning framework will be developed for the prediction tasks.

Study design

This is a non-randomized prospective observational study. Electronic data collection of continuous noninvasive arterial pressure waveform signals takes places with the CS/EV1000/HemoSphere system in patients admitted to the ED. This study is divided in two phases.
Phase 1:
A pilot phase comprising 200 ED patients. Standard of care is performed and timing and dosing is left to the judgement of the attending emergency physician.

Phase 2:
A non-randomized prospective observational data collection study in at least 1000 and maximally 1500 (dependent on the interim analysis) ED patients of with at least 20% sepsis and septic shock patients. An amendment will be submitted if there are changes to the protocol.

Study burden and risks

There are no additional risks or benefits associated with participation. There are no investigational devices used in this study. There are no additional risks associated with the use of the CS/EV1000/HemoSphere monitor other than

described in the Instructions for Use. There are also no risks associated with the study procedures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- >18 years of age
- Informed consent
- Admitted to the emergency department

Exclusion criteria

- Patients admitted to the trauma room
- Subjects will be excluded if noninvasive blood pressure cannot be measured with the finger cuff according to the Instructions for Use of the CS/EV1000 system.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-06-2023
Enrollment:	1500
Type:	Actual

Medical products/devices used

Generic name:	ClearSight fingercuff and EV1000 monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-05-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL80305.018.22