Prediction of Hemodynamic Instability in Patients Admitted to the ICU
A Prospective, Nonrandomized, Noninterventional Study for Clinical Data Collection

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28259

Source
Nationaal Trial Register

Brief title
PHYSIC

Health condition

Hypotension Probability Indicator (HPI) ICU patients with pressure waveform data.

Voorspeller van hemodynamische instabiliteit middels arteriële en non-invasieve drukcurve bij IC patiënten.

Sponsors and support

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Intervention

Outcome measures

Primary outcome

Hypotension Probability Indicator (HPI)

Study description

Background summary

Patients in the intensive care setting are often vulnerable to risk of developing cardiorespiratory instability. This is usually associated with markedly increased morbidity and mortality, which therefore makes the early identification of those patients likely to become unstable crucial [1].

Early instability typically manifests as subtle complex changes in multiple vital signs and hemodynamic variables, while more pronounced single parameter abnormalities occur later. Known methods are available to monitor invasive and noninvasive hemodynamic parameters to identify cardiorespiratory insufficiency to a high degree, however no such mechanism exists to evaluate or predict the likelihood of a patient becoming cardiorespiratory unstable [2].

Although hemodynamic instability is manifested by abnormalities in vital signs it reflects the interaction between the host’s physiological response, biological reserve, disease process and treatment interference. Thus, the expression of hemodynamic instability is neither straightforward nor linear in its interactions. Currently, resuscitation decisions are predicated on derangement of individual vital signs consistent with late stage of instability. Furthermore, it is often unclear what specific treatments will restore cardiorespiratory sufficiency. However, overt signs of instability often occur late and are often non-specific even when due to a single process. Early identification of circulatory insufficiency and its gross pathological cause will allow for earlier appropriate treatment resulting in reduced organ injury, improve outcome and more effective use of limited healthcare resources [1, 2].

Recently the Hypotension Probability Indicator (HPI) algorithm has been developed to determine the susceptibility of a patient to develop hypotension relating to multiple physiological cardiovascular parameters derived from the invasive and noninvasive arterial pressure signal in patients.

The goal of this study is to collect electronically data of continuous noninvasive and invasive arterial pressure waveform signals with the Clearsight System and Flotrac respectively to be used in advanced analysis for early detection and prediction of critical events in patients admitted to the intensive care, with the primary focus on predicting and avoiding hypotension. Patients admitted to the intensive care are subject to hemodynamic instability and critical events that could potentially be controlled and avoided in the intensive care setting. Use of advanced analysis techniques on multiple cardiovascular features extracted from the arterial pressure signal will allow for the ability to predict hypotensive events before they happen and empower treating physicians.

The HPI is a machine-learning algorithm that incorporates arterial BP waveform characteristics and their extracted features into a mathematical predictive model. The HPI model was developed and validated based on a large dataset of patients receiving invasive radial BP monitoring with use of invasive continuous monitoring (FloTrac®). The HPI predicted hypotension before the actual hypotensive event occurred with high sensitivity and specificity.

The main objective of this data collection initiative is to evaluate the previously developed Hypotension Probability Indicator (HPI) algorithm to determine the susceptibility of a patient to develop hypotension relating to multiple physiological cardiovascular parameters derived from the invasive and noninvasive arterial pressure signal in patients admitted to the intensive care.

The goal of this data collection study is to collect continuous noninvasive and invasive arterial pressure waveforms and hemodynamic cardiovascular data from patients admitted to the intensive care that will be used to validate the HPI in critically ill. The data collection will include continuous noninvasive and invasive arterial pressure waveform and hemodynamic parameters that will be collected digitally using the Clearsight en Flotrac monitor.

The purpose of this study is data collection of continuous noninvasive and invasive arterial pressure waveform signals in intensive care patients with the Clearsight and Flotrac monitor.

The collected digital pressure waveform data will be used to assess the feasibility of using the Clearsight continuous noninvasive and Fotrac invasive arterial pressure signal to predict hypotension using HPI during ICU admission by means of sensitivity and specificity.

Study objective

The purpose of this study is data collection of continuous noninvasive and invasive arterial

pressure waveform signals in intensive care patients with the Clearsight and Flotrac monitor. The collected digital pressure waveform data will be used to assess the feasibility of using the Clearsight continuous noninvasive and Fotrac invasive arterial pressure signal to predict hypotension using HPI during ICU admission by means of sensitivity and specificity.

Study design

1 measurement moment each patient, duration 8 hours

Intervention

Waveform data collection will be directly performed by the Clearsight system and Flotrac system and placed into a de-identified patient database for Edwards to access. In addition to waveform data, de-identified patients charts with intensive care clinical data and demographic information will be retrospectively collected, combined, and de-identified by an AMC research staff member.

Contacts

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Eligibility criteria

Inclusion criteria

Data of subjects will be included if the subjects meet the following criteria:

1. Subjects must be at least 18 years of age

2. Expected 8 hours ICU admission

3. Subjects or legal representatives must provide signed written informed consent (prospectively or retrospectively)

4. Arterial line present

Exclusion criteria

Subjects will be excluded if invasive BP cannot be measured with the Flotrac according to the Instructions for use of the Flotrac.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-07-2018
Enrollment:	500
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-07-2018
Application type:	First submission

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
NTR-new	NL7150
NTR-old	NTR7349
Other	Medische ethische toetsingscommissie AMC : W18_142#18.176

Study results