SepsiVit: trends and variability of vital signs in patients with sepsis

Gepubliceerd: 04-01-2017 Laatst bijgewerkt: 07-12-2022

Trends in and variability of vital signs reveal hidden information about the state and deterioration of the patient compared to absolute values of vital signs.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22189

Bron
NTR

Verkorte titel
SepsiVit

Aandoening

sepsis

Ondersteuning

Primaire sponsor: University Medical Center Groningen, The Netherlands
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient deterioration

Toelichting onderzoek

Achtergrond van het onderzoek

Despite the adoption of the Surviving Sepsis Campaign (SSC) guidelines, early goal-directed therapy and decades of research, sepsis-related morbidity and mortality remain high. One in five patients with infection or sepsis deteriorates within 48 hours, despite treatment. However, a clear tool to monitor patient deterioration in sepsis remains unclear. Monitoring changes in vital signs over time, so-called variability analysis, may provide information about response to treatment or signs of deterioration. Using continuous variability analysis could be used to determine prognosis and response to treatment of individual patients, i.e. to determine progression towards health or towards deterioration. Previous studies, mainly intensive care unit (ICU) and pilot studies, have shown reduction of heart rate variability (HRV) in critically ill patients and a relation with deterioration. However, the question remains if a reduction of HRV will be found in less ill patients presenting in the ED with infection or sepsis. The primary objective of the SepsiVit study is to find out if continuous HRV measuring during the first 48 hours of hospitalization in patients presenting to the ED with suspected infection or sepsis can provide an early warning signal for patient deterioration. Therefore, vital signs of adult medical patients presenting to the ED with suspected infection or sepsis will be monitored continuously for the first 48 hours of hospitalization with high sample rates using a bedside patient monitor. Variability analysis for HRV will be performed on the data to determine the relation between changes in HRV and patient deterioration.

Doel van het onderzoek

Trends in and variability of vital signs reveal hidden information about the state and deterioration of the patient compared to absolute values of vital signs.

Onderzoeksopzet

First 48-hours in the hospital

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

University Medical Center Groningen - Emergency Department

Vincent M. Quinten
HPC TA10 - PO Box 30001

Groningen 9700 RB
The Netherlands

Wetenschappelijk

University Medical Center Groningen - Emergency Department

Vincent M. Quinten
HPC TA10 - PO Box 30001

Groningen 9700 RB
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age >= 18 years

- Suspected or confirmed infection

- 2 or more SIRS criteria as defined by the 2001 International Sepsis Definition Conference

- Non-trauma patient

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Known pregnancy

- Patient is not admitted in the hospital

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	16-01-2017
Aantal proefpersonen:	171
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-01-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6037

Register	ID
NTR-old	NTR6168
Ander register	201500325 : METc 2015/164

Resultaten