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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON22189

**Source**
NTR

**Brief title**
SepsiVit

**Health condition**

sepsis

### Sponsors and support

**Primary sponsor:** University Medical Center Groningen, The Netherlands
**Source(s) of monetary or material Support:** fund = initiator = sponsor

### Intervention

### Outcome measures

**Primary outcome**

Patient deterioration

**Secondary outcome**

Influence of sepsis focus

# Study description

### Background summary

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.

### Study objective

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.

### Study design

First 48-hours in the hospital

### Intervention

None

# Contacts

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# Eligibility criteria

## Inclusion criteria

- Age >= 18 years

- Suspected or confirmed infection

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

- Non-trauma patient

## Exclusion criteria

- Known pregnancy

- Patient is not admitted in the hospital

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |

| | |
|---|---|
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 16-01-2017 |
| Enrollment: | 171 |
| Type: | Anticipated |

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 04-01-2017 |
| 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 | NL6037 |
| NTR-old | NTR6168 |
| Other | 201500325 : METc 2015/164 |

## Study results