Testing for sepsis in primary care

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20451

Source
Nationaal Trial Register

Brief title
TeSD-IT

Health condition

Sepsis; community-acquired infections; primary care

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: Funding by ZonMw, grantnumber 843001811
Material support by Nova Biomedical, ThermoFischer and Philips

Intervention

Outcome measures

Primary outcome

The primary outcome is diagnosis of sepsis within 72 hours of inclusion. The reference standard is an expert panel assessment (following the SEPSIS-3 definitions)

Secondary outcome

Severity of sepsis

30-day mortality

Hospital and ICU admission within 72 hours and length of hospital stay.

Cost-effectiveness

Study description

Background summary

The TeSD-IT study is a diagnostic and prognostic study, aiming for the developpement of a simple clinical decision tool for general practitioners. Clinical signs, C-reactive protein, procalcitonin and lactate are used for the development of the model. In total 1000 patients are included during out-of-hours GP home visits. The primary outcome is sepsis within 72 hours of inclusion.

Study objective

A structured use of clincal features in combination with bloodtests applicable as point-of-care(POC) tests, can improve recognition and outcome in sepsis patients

Study design

Follow-up is 30 days.

Intervention

The study is diagnostic and prognostic without an intervention. The following variables are obtained for the development of a clinical decision tool:

Age; temperature; blood pressure; heart rate; respiratory rate; oxygen saturation; rigors; acute clinical deterioration; C-reactive protein; procalcitonin; serum lactate

Contacts

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Eligibility criteria

Inclusion criteria

1)Adult patients (>18 years)

2)Home visit by a general practitioner from an out-of-hours service

3)Acutely ill patients with fever, confusion or general deterioration or otherwise suspected of a serious infection.

Exclusion criteria

1) No informed consent

2) Non-infectious cause of the acute complaints, e.g. stroke or myocardial infarction.

3) Hospitalisation less than 7 days before the home visit.

4) Condition that requires secondary care assessment in case of any signs of systemic infection (eg chemotherapy with possible neutropenia).

5)Terminal illness or other reason not to refer the patient to a hospital despite presence of a life-threatening condition.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-06-2018
Enrollment:	350
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48847
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6848
NTR-old	NTR7026
CCMO	NL63284.041.18
OMON	NL-OMON48847

Study results