Testing for sepsis in primary care: diagnostic and prognostic study investigating the potential benefits of point-of-care testing

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Ethical review	Approved WMO
Status	Completed
Health condition type	Infections - pathogen unspecified
Study type	Observational invasive

Summary

ID

NL-OMON48847

Source
ToetsingOnline

Brief title
TeSD-IT

Condition

- Infections - pathogen unspecified

Synonym
life-threatening infection, Sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: ZonMw,Nova Biomedical,Philips,Star-SHL,ThermoFisher

Intervention

Keyword: Diagnosis, Point-of-Care Testing, Primary care, Sepsis

Outcome measures

Primary outcome

The primary outcome is diagnosis of sepsis within 72 hours of inclusion.

Secondary outcome

Secondary outcomes are severity of sepsis, 30-day mortality, hospital and ICU

admission within 72 hours and length of hospital stay.

Study description

Background summary

Diagnosing sepsis in ambulatory primary care is challenging for GPs. The pre-hospital detection is known to be poor while early detection is important to prevent adverse outcome. Adaptation of diagnostic strategies from hospital settings, designed to include all sepsis patients for early treatment and further work-up, adheres the risk of a substantial increase of unnecessary referrals. Therefore diagnostic research in the primary care setting is needed to improve the detection in a cost-efficient manner. With the advent of POCT, these tests can now also be implemented in ambulatory primary care and even during home visits.

Our hypothesis is that a structured use of clinical features in combination with blood tests applicable as POC-tests, can improve recognition and outcome in sepsis patients.

Study objective

The objective of the study is to improve the detection of sepsis in primary care by developing a clinical decision rule for GPs, consisting of the most relevant clinical features and point-of-care (POC) measurements of biomarkers. This decision rule will help to decrease mortality and morbidity from sepsis as

well as reduce unnecessary referrals.

Study design

Prospective, multicentre, diagnostic and prognostic study.

Study burden and risks

From all patients venous blood samples (22ml total) will be obtained once directly after inclusion. A single questionnaire is send to all patients 30 days after inclusion. The burden for the included patients is therefore limited and involves a negligible risk. The target population are largely frail elderly patients, and some may be incapacitated due to the acute illness. Excluding the most severely ill patients must be prevented to be able to develop a valid clinical decision rule. Therefore, the screening procedures for patient recruitment have been designed to prevent selection bias without compromising informed consent or medical treatment.

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

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 invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	23-06-2018
Enrollment:	1000

Type:	Actual

Ethics review

Approved WMO Date:	16-05-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-06-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-10-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Not approved Date:	27-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-06-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-10-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-04-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20451
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63284.041.18

Study results

Date completed: 07-04-2020

Results posted: 06-10-2021

Actual enrolment: 357

First publication
01-09-2021