

Predicting microbiological and clinical outcomes of patients with suspected bacteremia presenting at emergency department: a prospective observational study

Gepubliceerd: 02-07-2019 Laatste bijgewerkt: 18-08-2022

Using the clinical and biochemical markers that can exclude the presence of bacterial infections, the hypothesis is that a lot of blood cultures can be reduced with minimal loss of sensitivity for true positive blood cultures which can help reduce...

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

Samenvatting

ID

NL-OMON23345

Bron

NTR

Verkorte titel

PrediCTed

Aandoening

Febrile illnesses, sepsis

Ondersteuning

Primaire sponsor: Haga Teach Hospital Research Board

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Presence of positive blood cultures • Time to positivity of blood culture

Toelichting onderzoek

Achtergrond van het onderzoek

In daily practice at the emergency department (ED), patients often present with febrile illnesses. Fever is a sign with little specificity and may reflect a simple local infection, but may also indicate the beginning of a sepsis cascade. Physicians are usually cautious since infections and sepsis (including septic shock) are associated with significant morbidity and mortality. Therefore, according to sepsis guidelines, microbiological blood and urine cultures are routinely taken and empiric antibiotic therapy will be started as soon as possible [1]. However, blood cultures in patients with suspected infection have a low sensitivity for bacteremia since <10% shows growth of bacteria [1-3]. Furthermore, the specificity of blood cultures is limited by contamination, leading to antibiotic overuse, avoidable side effects such as the emergence of microbial resistance. At last, these routine examinations contribute to the increase in health care costs.

In the recent years, various studies examined the diagnostic accuracy of various clinical parameters to predict bacteremia including vital signs and biochemical parameters such as white blood cell count and CRP. More recently, PCT seemed to be of additional value for physicians [4]. However, though current published data and meta-analyses show that PCT is a helpful biomarker for early diagnosis of sepsis, its use as a routine diagnostic tool for bacterial infection is still questionable as the sensitivity and specificity of PCT for diagnosing sepsis or bacteremia is 0.77 and 0.79, respectively [5]. Yet, a lot of studies used for these analyses did not contain bacteremia as the primary endpoint and patients only suffering from one type of infection were included (such as CAP, UTI's etc.) [6-8]. According to more recent studies, PCT values may aid physicians in various ways by helping to rule out or increase the probability of bacterial infections. In particular, low PCT levels seemed useful to rule out the presence of bacterial infections and bacteremia in different clinical settings and can therefore limit the use of blood cultures and unjustified empiric antibiotic therapy. More importantly, PCT may discriminate between true bacteremia and CNS staphylococci blood cultures in patients without suspicion of intravascular catheter/device-associated infection [9, 10]. Furthermore, PCT was considered more valuable to be used in clinical practice than CRP for predicting bacterial infections in febrile illnesses.

Recently Laukemann et al examined the use of clinical parameters (the Shapiro score) and biochemical parameters including PCT, CRP, WBC, NLCR and RDW creating a prediction model for the presence of bacteremia with good discriminative performance [3, 11]. Limiting blood cultures only to patients with a certain score or PCT value in this study, reduced negative sampling by 20.2% while still identifying 100% of positive cultures. Furthermore, PCT also showed highest AUC for LRTI's and infections with gram-negative

bacteria as compared to SSTI's.

Using the clinical and biochemical markers that can exclude the presence of bacterial infections, the hypothesis is that a lot of blood cultures can be reduced with minimal loss of sensitivity for true positive blood cultures which can help reduce costs and most importantly won't lead to increased antimicrobial resistance because of unjustified use of antibiotics.

Recently, the safe reduction of blood cultures by using PCT has been demonstrated in a randomized trial at ICUs [12]. However, the question remains whether this also applies at the setting of EDs.

We aim to analyze the same clinical and biochemical parameters in a more heterogeneous group of patients presenting at the ED suffering from febrile illness with a new prospective, observational study. Current practice of patients will not be different than usual practice which means that blood cultures will be drawn in patients presenting with febrile diseases with determination of various biomarkers such as urea, kidney, liver assay, CRP, WBC and PCT. PCT however will not be available at presentation and these results will only be determined for the sake of this study.

Doel van het onderzoek

Using the clinical and biochemical markers that can exclude the presence of bacterial infections, the hypothesis is that a lot of blood cultures can be reduced with minimal loss of sensitivity for true positive blood cultures which can help reduce costs and most importantly won't lead to increased antimicrobial resistance because of unjustified use of antibiotics.

Recently, the safe reduction of blood cultures by using PCT has been demonstrated in a randomized trial at ICUs [12]. However, the question remains whether this also applies at the setting of EDs.

Onderzoeksopzet

30 days for registration of clinical/biochemical and follow-up parameters.

Contactpersonen

Publiek

HagaZiekenhuis
Soufian Meziyeh

0031641667371

Wetenschappelijk

HagaZiekenhuis
Soufian Meziyeh

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

A subject is eligible for inclusion if all of the following criteria apply:

1. Competent patient aged 18 years or above presenting at ED
2. Withdrawal of blood culture at ED

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A subject is not eligible for inclusion if all of the following criteria apply:

1. Patients younger than 18 years old

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	17-04-2019
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 02-07-2019

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	NL7852
Ander register	METC ZWH : METC 17-125

Resultaten