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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23345

Source
NTR

Brief title
PrediCTed

Health condition

Febrile illnesses, sepsis

Sponsors and support

Primary sponsor: Haga Teach Hospital Research Board
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

• Total number of hospitalization days during 1 month of follow-up • ICU-admission rate • Positive urine cultures • Hospital discharge destination • Clinical cure rate • Cost-effectiveness • Definite clinical and microbiological diagnosis • Presence of bacterial infection (yes/no) • Hospital mortality rate (and 30-day mortality if available in electronic patient file)

Study description

Background summary

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-negatieve 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 whethers this also applies at the setting of EDs.
We aim to analyze the same clinical and biochemical parameters in a more heterogenous 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.

Study objective

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 whethers this also applies at the setting of EDs.

Study design

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

Contacts

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Eligibility criteria

Inclusion criteria

A subject is eligle 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

Exclusion criteria

A subject is not eligle for inclusion if all of the following criteria apply:
1. Patients younger than 18 years old

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-04-2019
Enrollment:	1000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-07-2019
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	NL7852
Other	METC ZWH : METC 17-125

Study results