Appropriate use of Blood Cultures in the emergency department through machine learning: a randomized controlled trial.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON53669

Source
ToetsingOnline

Brief title
ABC Study

Condition

- Bacterial infectious disorders

Synonym
Bacteraemia; bloodstream infection

Research involving
Human

Sponsors and support

Primary sponsor: Acute Interne Geneeskunde
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blood cultures, emergency department, machine learning

Outcome measures

Primary outcome

Non-inferiority regarding 30-day mortality.

Secondary outcome

The key secondary outcomes are:

Non-inferiority regarding hospital admissions, length of stay in hospital and

death in hospital.

Furthermore, superiority is examined in a large group of different outcome

measures (either patient-, process- or model-related).

Study description

Background summary

Blood cultures are important to detect a bacterium in the bloodstream. Although such an infection of the bloodstream is uncommon, the blood culture is often used for fear of missing this diagnosis. As a result, only about 15% of these cultures yield anything in the emergency room. Unfortunately, half of this yield is false positive (a bacterium is found, but it is not the cause of the infection). Patients with false-positive cultures often receive unnecessary antibiotics, undergo more procedures and, on average, spend longer in hospital.

Our research group has developed a prediction model that can predict the probability of a positive blood culture. In this study we want to omit the blood culture analysis if the chance of a positive result is very small. Preliminary studies have shown that about 30% of blood cultures can safely be cancelled, while we miss an infection in less than 1% of the cases. If we analyse 30% less blood cultures, there will also be less false positive

results. This allows us to avoid unnecessary antibiotic administration, procedures and hospitalization. In this study we want to see whether this can indeed be done safely and how great the potential benefits are for the patient.

Study objective

The aim of this study is to see whether we can safely use blood cultures more efficiently. By using a prediction model, we support the clinical decision to analyse a blood culture. If the chance that this culture yields a positive result is very small, then we want to withhold this analysis.

Study design

A multicenter randomized controlled non-inferiority trial.

Intervention

The use of the blood culture prediction model, to omit blood cultures analyses at less than 5% chance of a positive culture.

Study burden and risks

The burden on the patient is minimal, there are no study activities. There is a minimal risk that omitting the blood culture analysis could lead to a situation in which we cannot treat the patient with an adequate antibiotic, while we could have done this with a culture result. However, from previous literature and validation of our prediction model, it seems that this risk is extremely small and does not outweigh the potential benefits.

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

All adult patients who have a clinical indication for a blood culture analysis (according to the treating physician) in the emergency department.

Exclusion criteria

• Central Venous Line (CVL) in situ
• Neutrophil count < 0.5 * 109/L
• Candidemia or S. aureus bacteraemia in the past 3 months.
• Mostly likely diagnosis of endocarditis/spondylodiscitis/infected prosthetic material
• Incapacitated patients who cannot provide informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-02-2024
Enrollment:	7584
Type:	Actual

Medical products/devices used

Generic name:	Blood Culture Prediction Tool
Registration:	No

Ethics review

Approved WMO Date:	04-08-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-10-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL81971.000.23