Early detection of bacteria in bloodstream infections using molecular diagnostics: implications for patient care

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

Summary

ID

NL-OMON33903

Source
ToetsingOnline

Brief title
Early diagnosis of bloodstream infections

Condition

- Bacterial infectious disorders

Synonym
bloodstream infection, sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Medische Microbiologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bloodstream, Diagnosis, Early, Infections

Outcome measures

Primary outcome

The primary endpoint is the reduction in time that broad spectrum or

inappropriate antibiotic therapy is used.

Secondary outcome

Secondary outcomes are:

- Length of hospital stay

- Implementation of the therapy advised by medical microbiologists

- Adverse effects of antibiotic use

- Mortality

- Economic evaluation

Study description

Background summary

Bloodstream infections (bacteraemia) have a mortality of up to 25%. Starting appropriate therapy empirically has been found to reduce mortality. Therefore, (combinations of) broad spectrum antibiotics are used. However, broad spectrum antibiotics have the disadvantage of not covering all bacteria, selection of antibiotic resistant bacteria and increased drug toxicity.

Study objective

In this study we aim to determine whether the use of a novel molecular technique (real-time PCR) decreases the time during which empirical broad-spectrum antibiotics are used in comparison to the conventional identification techniques of blood cultures.

Study design

Randomised, blinded clinical trial

Intervention

After randomisation, test results obtained by either the PCR test or the conventional methods will be conveyed and antibiotic therapy will be adjusted accordingly. Demographic and follow-up data will be monitored in a standardised way.

Study burden and risks

The burden from participation in this study is very low, no extra blood has to be drawn and in order to obtain information about the patient the chart will be used. Patients randomised for the conventional method (the control group) will experience no benefits or disadvantages from their participation in this study. Patients randomised for the PCR-based test may profit from participation, since they can be treated with an adequate antibiotic sooner. The risk of the new test being less accurate than the conventional method is small. We found that the agreement of the PCR-based test with the results of the gold standard is 95% for Gram-negative rods and 96% for Gram-positive cocci. The agreement of the conventional method with the gold standard is about 97%. To minimise the risk of a false diagnosis, blood cultures in the group of the PCR-based method will also be tested with the conventional method, so treatment can be adjusted in case of discrepant results.

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 consecutive patients of 18 years and older in the University Hospital Maastricht with a positive blood culture, including mentally incapacitated patients if their legal representatives signed informed consent for participation in this study.

Exclusion criteria

A positive blood culture in the previous three days

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	22-10-2009
Enrollment:	340
Type:	Actual

Ethics review

Approved WMO Date:	14-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-09-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL22673.068.08