Early detection of bacteria in bloodstream infections: implications for patient care.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24453

Source
NTR

Brief title
DOBBI (Diagnosis Of Bacterial Bloodstream Infections)

Health condition

Bloodstream infection, sepsis, rapid antibiotic susceptibility testing

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Profileringsfonds azM

Intervention

Outcome measures

Primary outcome

Primary endpoint is reduction in time that a broad-spectrum or inappropriate antibiotic therapy is used.

Secondary outcome

Secondary outcomes:

1. Length of hospital stay;

2. Implementation of the advise of the medical microbiologist regarding antibiotic therapy by the patients' physician;

3. Adverse effects of antibiotic use;

4. Mortality;

5. Economic evaluation.

Study description

Background summary

Blood stream infections have a high mortality, up to 25%. Since quick adequate therapy reduces mortality, broad spectrum antibiotics are used as empirical therapy. However, this strategy may lead to problems such as selection of antibiotic resistant bacteria, higher risk of drug toxicity and the risk of not covering the causative micro-organism. Early identification of the causative micro-organism and rapid determination of the antibiotic susceptibility pattern will narrow down the antibiotic therapy and reduce the time that broad antibiotic therapy is given.

The objective of this randomised, blinded clinical trial is to evaluate the influence of a PCR-based diagnostic test for antibiotic susceptibility in bacteraemia patients.

All patients 18 years and older admitted to the Maastricht University Medical Center with grown blood cultures are eligible for inclusion. Exclusion criteria are: a blood culture containing streptococci, coagulase-negative staphylococci, anaerobes or multiple species or a positive blood culture in the previous 3 days.
Patients are randomised for antibiotic therapy according to either the rapid PCR-based method or the conventional method (conventional culture techniques).

Primary endpoint is reduction in time that a broad-spectrum or inappropriate antibiotic is used. Secondary outcomes are implementation of the antibiotic advice, length of hospital stay, adverse effects of antibiotic use, mortality and economic evaluation.

Study objective

We hypothesize that earlier diagnosis in bloodstream infections results in earlier initiation or

adaptation of the empirically started broad-spectrum antibiotics and may lead to an improved patient outcome, decrease in costs and reduction of selection of antibiotic-resistant bacteria.

Study design

1. At inclusion, baseline characteristics, signs of infection (lab results, X-rays, previous cultures), reason for taking a blood culture, previous infections and previous use of antibiotics will be recorded;

2. 9 hours after inclusion: reporting of results of the new methods;

3. 24 hours after inclusion: registration of signs of infection and reporting of the results of the conventional method;

4. At discharge or death of the patient: registration of antibiotics used during hospital stay, side-effects of antibiotics, infections during hospital stay and length of stay or cause of death.

Intervention

In patients randomised for the intervention group, a new, rapid method for antibiotic susceptibility testing directly on positive blood cultures will be used. This method combines culture and PCR. The PCR is used to assess growth of bacteria in medium in the presence of an antibiotic. In this group, the results of this rapid method will be reported to the attending physician. In the control group, results of conventional methods (i.e. BD Phoenix (automated antibiotic susceptibility testing), E-test and disk diffusion) will be reported.

Contacts

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Eligibility criteria

Inclusion criteria

All patients in the Maastricht University Medical Center with a positive blood culture are eligible for inclusion.

Exclusion criteria

1. Age under 18;

2. A blood culture containing streptococci, coagulase-negative staphylococci, anaerobes or multiple species;

3. A positive blood culture in the previous 3 days.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	12-10-2009
Enrollment:	340
Type:	Anticipated

Ethics review

Positive opinion Date:	06-10-2009
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	NL1926
NTR-old	NTR2043
Other	MEC azM/UM : MEC 08-2-071
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A