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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24453

Bron
NTR

Verkorte titel
DOBBI (Diagnosis Of Bacterial Bloodstream Infections)

Aandoening

Bloodstream infection, sepsis, rapid antibiotic susceptibility testing

Ondersteuning

Primaire sponsor: Maastricht University Medical Center
Overige ondersteuning: Profileringsfonds azM

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Department of Medical Microbiology
Maastricht University Medical Center
P.Debeyelaan 25
P.F.G. Wolffs
Department of Medical Microbiology
Maastricht University Medical Center
P.Debeyelaan 25
Maastricht 6229 HX
The Netherlands
+31 (0)43-3876644

Wetenschappelijk

Department of Medical Microbiology
Maastricht University Medical Center
P.Debeyelaan 25
P.F.G. Wolffs
Department of Medical Microbiology
Maastricht University Medical Center
P.Debeyelaan 25
Maastricht 6229 HX
The Netherlands
+31 (0)43-3876644

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	12-10-2009
Aantal proefpersonen:	340
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-10-2009
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	NL1926
NTR-old	NTR2043
Ander register	MEC azM/UM : MEC 08-2-071
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A