Comparison of novel assays for the molecular detection and quantification of bacteria in patients with bloodstream infections

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To evaluate molecular assays for the detection and quantification of bacterial DNA in blood of patients with bacteraemia. Objectives are to determine the diagnostic performance of five molecular assays for the detection of bacteraemia in patients...

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

Summary

ID

NL-OMON39300

Source
ToetsingOnline

Brief title
COMBI-study

Condition

- Bacterial infectious disorders

Synonym
bacteraemia, bloodstream infection, sepsis (in case blood stream infection sepsis is regularly diagnosed)

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: bacteraemia, bloodstream infection, molecular detection, PCR

Outcome measures

Primary outcome

The diagnostic performance of each molecular assay is determined by the sensitivity, specificity, positive predictive value, negative predictive value as compared to culture as a golden standard. Inter-assay variation is determined by measure of agreement and calculation of kappa value.

Secondary outcome

To assess the putative applicability of the molecular assays in routine molecular diagnostics with regard to costs, hands on time and difficulty of the protocol in routine use.

Study description

Background summary

Bloodstream infections are a major cause of mortality and morbidity. Current routine diagnosis by blood culture is hampered by a fairly long time to positivity and reduced sensitivity due to already initiated antibiotic therapy. Molecular diagnosis of bloodstream infection may offer a faster alternative to blood culture irrespective to antibiotic treatment. In addition, bacterial DNA load might be an important marker of severity of infection. This study investigates the performance of several new assays for the detection in patients with bacteraemia.

Study objective

To evaluate molecular assays for the detection and quantification of bacterial DNA in blood of patients with bacteraemia. Objectives are to determine the diagnostic performance of five molecular assays for the detection of bacteraemia in patients and to evaluate the relationship between bacterial DNA load (BDL), quantitative culture and culture time-to-positivity in patients with bacteraemia.

Study design

This study is an observational study in patients with bacteraemia. It is designed to evaluate five molecular assays, qualitative blood culture and quantitative blood culture for the detection and quantification of bacteraemia in patients. For purpose of the study blood is drawn once from patients with bacteraemia. The study will be performed at the VU university medical center, department of medical microbiology and infection control, Amsterdam, The Netherlands.

Study burden and risks

For the purpose of this study one venipuncture (in incapacitated patients blood is obtained through a central catheter) is performed and approximately 50ml blood is obtained. The risk and burden of such venipuncture is considered to be very limited since the amount of blood is small considering the total blood volume. In addition, severely anaemic patients are not included in this study. No other participation is required from the patient with the exception of a very limited physical examination. Patient information is retrieved from the medical record. Patients will not have any benefit from participation in the study, but this study will generate important information regarding the diagnostics of bloodstream infections in the future.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 18 years
- Bacteraemia with at least one blood culture with growth of Gram-negative bacteria or Gram-positive cocci in chain observed with microscopy.
- Bacteraemia with at least one blood culture with growth of Gram-positive cocci (in clusters) and at least one of the following syndromes suggestive of S. aureus infection: arthritis, wound infection, thrombophlebitis, meningitis, soft tissue infection, vertebral osteomyelitis, splenic abscess or other microbiological evidence for S. aureus infection

Exclusion criteria

- Blood culture obtained >48 hours
- Intravenous antibiotic therapy >48 hours
- Haematological disorder
- Anaemia (an Hb below 5.5 mmol/L)
- Participation in BLENT-study of patients with endocarditis
- Previous participation in this study

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-07-2013
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-06-2013
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	NL40998.029.12