Molecular detection of the bacterial load as a diagnostic and monitoring tool for optimal antibiotic treatment in endocarditis

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Primary objectives:- Evaluation of the value of mBL as a diagnostic tool for bacterial endocarditis.- Evaluation of the value of mBL as a monitoring tool during treatment for bacterial endocarditis.- To obtain data on the kinetics of mBL related to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Observational invasive

Summary

ID

NL-OMON35768

Source
ToetsingOnline

Brief title
Bacterial Load during ENdocarditis Therapy (BLENT)

Condition

- Cardiac valve disorders
- Bacterial infectious disorders

Synonym
cardiac valve infection, endocarditis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bacterial load, endocarditis, molecular detection

Outcome measures

Primary outcome

- Determination of the diagnostic value of mBL for the diagnosis of bacterial endocarditis with endocarditis defined according to Duke criteria

- Prognostic value of mBL in patients with endocarditis according to Duke criteria with regard to the occurrence of a complicated course

- A descriptive model of the kinetics of mBL related to infectious parameters (CRP, WBC, PCT) in patients with an uncomplicated treatment course of bacterial endocarditis.

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Secondary outcome

- Determination of the diagnostic value of mBL for the diagnosis of bacterial endocarditis compared to blood culture results and laboratory markers (e.g. CRP, procalcitonin, WBC).

- Prognostic value of mBL in patients with endocarditis according to Duke criteria with regard to other outcome parameters (mortality, surgery)

- Correlation of mBL at start of therapy with clinical severity scores (PITT

bacteremia score, APACHE II score).

- Correlation of mBL at start of therapy with the occurrence of a complicated

treatment course at a later time point.

- Daignostic and prognostic value of 'host response markers' in patients with

bacterial endocarditis.

Study description

Background summary

Endocarditis is a serious life-threatening condition. Rapid diagnosis and monitoring of response to treatment is very important, because of the significant risk of infection-related complications and/or therapeutic failure. Diagnosis often takes several days due to blood culturing which causes a delay in instalment of appropriate treatment. Commonly used laboratory parameters for monitoring such as CRP and leucocytes are not specific enough to detect a complicated treatment course. Molecular detection of the bacterial load (mBL) has been shown to be pathogen-specific, and is directly correlated to severity of disease in bloodstream-related infections. It has the potential to be used as a rapid tool (<5hrs) for diagnostics and therapeutic monitoring of patients with endocarditis. This could lead to earlier diagnosis and detection of a complicated treatment course, which enables pre-emptive strategies to improve outcome.

Study objective

Primary objectives:
- Evaluation of the value of mBL as a diagnostic tool for bacterial endocarditis.
- Evaluation of the value of mBL as a monitoring tool during treatment for bacterial endocarditis.
- To obtain data on the kinetics of mBL related to infectious parameters in patients with bacterial endocarditis.

Secondary Objectives
- Value of mBL to determine the severity of bacterial endocarditis at start of therapy.
- Value of mBL to predict treatment-course at start of therapy for bacterial endocarditis.
- Evaluation of markers of the host response in patients with bacterial

endocarditis.

Study design

This study is a multicenter prospective observational study. All adult patients who are suspected for bacterial endocarditis, and are hospitalized or presenting at the emergency department in the participating hospitals, are eligible for the study. Routine diagnostic work-up to will be performed in these patient to confirm or reject the diagnosis bacterial endocarditis. These patients will be asked for informed consent to participate in this study.
Enrolled patients suspected for bacterial endocarditis will be followed up by performing serial blood measurements and by recording clinical information from the patients medical record and the automated patient data management system.
In the first week of follow up daily blood sampling is performed. Follow up sampling will be continued in patients in whom the treating physician continues treatment for endocarditis. Follow up is continued during endocarditis therapy.
If endocarditis is rejected, sampling is discontinued instantly.

Study burden and risks

Patient burden for this study is limited since routine blood tests are performed regularly in patients with endocarditis. Therefore sampling for this study mostly entails adding an extra EDTA-bottle to the routine procedure. To keep patient burden low we have set a maximum per patient of six extra venepunctures for purpose of the study.
The amount of blood obtained from included patients for purpose of this study will usually be between 96-192ml. The maximum amount of blood obtained for study purposes is set at 250 ml.

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

- Adult patients (*18 years) with suspected endocarditis, admitted in one of the participating hospitals
- Written informed consent is obtained

Exclusion criteria

- Failure to obtain written informed consent to participate
- Endocarditis caused by Coxiella burnettii (Q-fever)
- An Hb below 5.0 mmol/L
- Death before first sample is obtained

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2011
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	18-04-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-11-2011
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

ID: 27689
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL35425.029.11
Other	TC = 2930
OMON	NL-OMON27689