Gene expression in sepsis and sterile sirs in pediatric patients after cardiac surgery

Published: 09-09-2009
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To differentiate between gene expression in sepsis and sterile sirs.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32059

Source
ToetsingOnline

Brief title
Gene expression in sirs and sepsis

Condition

- Congenital cardiac disorders
- Helminthic disorders

Synonym
blood stream infection, sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac surgery, gene expression, sepsis, sirs

Outcome measures

Primary outcome

To differentiate between sepsis and sterile SIRS by means of gene expression.

Secondary outcome

Translate the genes that are expressed in sepsis into a protein which may be

used as a diagnostic test in the future.

To reduce the unnecessary use of antibiotics in patients after cardiac surgery

To prohibit the adverse effect of extensive use of antibiotics such as

bacterial resistance or developing superinfection as a result of

microbiological inbalance.

To reduce procedures which are a result of suspecting an infectious cause,

such as unnecessarily changing CVC*s

Study description

Background summary

Because of the high risk of infection and endocarditis in patients after cardiac surgery,
there is a low threshold for starting antibiotics when infection is suspected, or changing the CVC when catheter related infection is suspected.
Systemic Inflammatory Response Syndrome (SIRS) appears similar clinically, irrespective if it is caused by an infectious (sepsis) or non-infectious (sterile SIRS) etiology.
In pediatric patients after cardiac surgery there is a low threshold for the use of antibiotics when infection is suspected. However, in a lot of cases no causative microorganism can be demonstrated. Probably, the symptoms are reflecting SIRS, which can for example, be the result of using cardiopulmonary bypass during the procedure.

Often unnecessary antibiotics will be started. Extensive use of antibiotics might cause adverse effects such as bacterial resistance and infections with candida or aspergillus species.
Every seven days, the central venous catheter is electively changed, although in literature there is no evidence found for this routine. In case of suspected (blood stream) infection, often the CVC will be replaced, which can lead to mechanical or other omplications, and also another vessel might be sacrificed due to obstruction.
Despite the similar phenotypic expression, genotypic expression may differ in case of different etiologies causing SIRS. This hypothesis is verified by several studies in critical ill adults with all kinds of underlying diseases.
Besides the arguments mentioned above, differentiation between sepsis and sterile SIRS is important considering the fact that the mortality of sepsis is much higher than that of uninfected SIRS.
One study showed a unique pattern of gene expression in the neonatal myocardium of neonates after cardiac surgery for right heart obstructive lesions. However it*s not clear whether this is age dependent, or reflecting underlying disease.
In several other publications (in adults), gene expression profiles after cardiopulmonary bypass and cardioplegic arrest were described.

Study objective

To differentiate between gene expression in sepsis and sterile sirs.

Study design

This is an observational explorative study that will be conducted at the operating room (OR) and pediatric intensive care unit (PICU) at LUMC, Leiden, the Netherlands.
20 patients will be enrolled in the study, undergoing cardiac surgery with bypass for congenital heart defects.
Residual blood from arterial samples will be collected on the OR (moment of study entry), immediate after admittance on the PICU, 12, 24 and 48 hours later. Taking blood samples at these timepoints is routine patient practice.
Genetic expression will be analyzed, in order to investigate if there is a differencein expression in patients with SIRS or Sepsis.
The diagnosis of Sepsis and SIRS are based on the clinical criteria as defined by the Members of the International consensus conference on pediatric sepsis.

Study burden and risks

not applicable

Contacts

Public
Leids Universitair Medisch Centrum

albinusdreef 2
2300 RC Leiden
Nederland
Scientific
Leids Universitair Medisch Centrum

albinusdreef 2
2300 RC Leiden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Pediatric patients who need surgery for congenital heartdefects, and will need cardiopulmonary bypass.

Exclusion criteria

steroid administration, participation in other crt

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	09-09-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL19974.058.07