

Molecular mechanisms in the host-pathogen interaction in neonates; an approach on the level of gene and protein expression

Published: 23-11-2006

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To investigate the gene and protein expression of neonates suffering from CoNS late-onset sepsis.

Ethical review	Not approved
Status	Will not start
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON30013

Source

ToetsingOnline

Brief title

Gene and protein expression in neonates with staphylococcal sepsis

Condition

- Bacterial infectious disorders

Synonym

blood stream infection

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: coagulase-negative staphylococci, immune respons, neonates, sepsis

Outcome measures

Primary outcome

Difference in genomic transcription profiles and protein profiles between patients and controls.

Secondary outcome

To gain insight in similarities and differences in gene expression profiles between neonates suffering from CoNS sepsis and children suffering from meningococcal sepsis.

Study description

Background summary

Nosocomial infections caused by coagulase-negative staphylococci occur frequently in neonates, because of an immature immune system and invasive procedures. Studying the immune system during infection may lead to better understanding of the pathophysiology and consequently to adequate (future) prevention measures.

Study objective

To investigate the gene and protein expression of neonates suffering from CoNS late-onset sepsis.

Study design

Monocenter, non-therapeutic, observational study.

Study burden and risks

A maximum of three blood samples of 1 ml each will be drawn from the study subject. Blood will be drawn from existing arterial lines if present, or

combined with medically necessary blood takings. Patients will not directly benefit from this study, although patients in the future might.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Admission on neonatal intensive care unit
Clinical signs of late-onset sepsis
Weight at least 750 g

Exclusion criteria

Birth weight < 750 g

No informed consent

Positive blood culture for bacteria other than coagulase-negative staphylococci

Study design

Design

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

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Not approved	
Date:	23-11-2006
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL13424.078.06