The protective role of the administration of antibiotics on the occurrence of sepsis after removal of ventral venous catheters in neonates.

Published: 11-03-2008
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To decrease the incidence of sepsis after removal of central venous catheters in the neonatal intensive care unit.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON31570

Source
ToetsingOnline

Brief title
Sepsis prevention after removal of CVC in neonates.

Condition

- Bacterial infectious disorders

Synonym
sepsis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Central venous catheter, neonate, Sepsis

Outcome measures

Primary outcome

All neonates are followed for at least 72 hours after removal of the central

venous catheter to study the occurrence of clinical signs of infection and

follow laboratory parameters indicative of infection (C-reactive protein,

procalcitonin, blood leukocytes count).

Secondary outcome

na

Study description

Background summary

Retrospective study among neonates with a central-venous catheter showed taht sepsis occurred frequently within 72 hours after removal of the catheter and that sepsis was reduced in the group of infants who received antibiotics at the moment of removal of the catheter. Therefore, a prospective study is suggested on the protective effect of the administration of antibiotics on the incidence of sepsis following a strict protocol.

Study objective

To decrease the incidence of sepsis after removal of central venous catheters in the neonatal intensive care unit.

Study design

During the period of 1 year all neonates with a central venous catheter are randomized to either receive antibiotics at removal of the catheter or not receive antibiotics. The choice of antibiotics is based on the most frequently isolated microorganisms that cause neonatal late-onset sepsis, coagulase-negative staphylococci. These microorganisms are usually susceptible for cefazolin. In case of increased risk for resistance, vancomycin is

administered.
Clinical data of all patients and data on the central venous catheters (type, insertion site, age at insertion, duration) are collected prospectively. Furthermore, data on antibiotic use are collected, the reason for the administration af antibiotics and clinical signs of infection when they occur and the results of the blood culture in case of sepsis. A blood culture yielding coagulase-negative staphylococci is considered positive when the culture became positive within 48 h.

Intervention

Neonates are randomized to either a group that receives antibiotics at the moment of removal of the catheter or to a group that does not receive antibiotics.

Study burden and risks

na

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Insertion of central venous catheter

Exclusion criteria

None

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	266
Type:	Anticipated

Ethics review

Approved WMO Date:	11-03-2008
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL17110.041.07