Reducing the prescription of antibiotics in newborn infants, suspected for an early onset sepsis.

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Is it possible with the course of cytokines in the first two days of life to start antibiotics selectively in infants suspected for an EOS (early onset sepsis) and to stop prescribing antibiotics in infants who already receive antibiotics

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22612

Bron
Nationaal Trial Register

Verkorte titel
RAP study

Aandoening

Early onset sepsis
Neonatal sepsis
Cytokines
Antibiotics
Vroege infectie
Neonatale infectie
Cytokinen
Antibiotica

Ondersteuning

Primaire sponsor: No sponsor
Overige ondersteuning: Doelmatigheidsfonds UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

proven EOS vs. no EOS

EOS is defined as a positive blood culture taken within 48 hours after birth. Cultures positive for organisms considered as contaminants (such as corynebacterium) are excluded.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Due to suspected Early Onset Sepsis (EOS) newborn infants receive frequently antibiotics which have several side effects. EOS, defined as a sepsis starting within the first 2 days of life, is a severe and life-threatening disease. The mortality when untreated is around 100%. EOS is difficult to diagnose. The first clinical symptoms of a sepsis are non-specific and may be subtle. The presence or absence of maternal risk factors may be related to EOS, but do not predict the occurrence of an EOS. Common laboratory parameters are not sensitive enough to predict or exclude the diagnosis of EOS. The golden standard to detect a neonatal sepsis is a blood culture but results are definite only after 48-72 hours.

Given the difficulty of a clinical diagnosis of EOS, immediately starting antibiotic therapy is the recommended approach in all infants with suspected EOS. This approach will cause, in retrospect, “unnecessary” treatment in many infants.

Objective:

To develop a new diagnostic model to reduce unnecessary antibiotic treatment, which can be tested in the near future.

Study design:

Non-therapeutic observational study.

Study population:

1. Inborn infants admitted to a pediatric or a maternity ward direct postnatally and in whom an EOS cannot be excluded.

2. Inborn infants admitted to a pediatric ward direct for glucose measurements and who is not suspected for an EOS.

Main study parameters/endpoints:

The primary outcome parameters are:
EOS versus no EOS.

The primary study parameters are the course of cytokines (IL-2, IL-4, IL-6, IL-8, IL-10, IL-12, TNF-á, IFN-ã, RANTES en IP-10) direct post partum, 4 hours post partum, 24 hours post partum and 48 hours post partum.

Doel van het onderzoek

Is it possible with the course of cytokines in the first two days of life to start antibiotics selectively in infants suspected for an EOS (early onset sepsis) and to stop prescribing antibiotics in infants who already receive antibiotics

Onderzoeksopzet

Cytokine measurements:

NS: 5 ml cord blood will be taken for cytokine measurements and analyzed for DNA polymorphism, putatively involved in EOS.

T1: Direct post partum when blood is taken for clinical diagnostics 0.2 ml will be taken for cytokine and CRP measurements.

T2: Four hours after T1 when blood is taken for clinical diagnostics 0.2 ml will be taken for cytokine measurements.

T3: 24 hours post partum when blood is taken for clinical diagnostics 0.2 ml will be taken for cytokine and CRP measurements.

T4: 48 hours post partum when blood is taken for clinical diagnostics 0.2 ml will be taken for cytokine and CRP measurements.

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. A newborn infant who is admitted to a pediatric or to a maternity ward and in whom an EOS cannot be excluded.

2. Informed consent of the parent or legal guardian.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Newborn infant older than 6 hours.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-01-2008
Aantal proefpersonen:	900
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-03-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1212
NTR-old	NTR1257
Ander register	METC : 2007-149
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A