Safely reduce newborn antibiotic exposure with the early-onset sepsis calculator: a cluster randomized study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52299

Source
ToetsingOnline

Brief title
EOS Calculator RCT

Condition

- Bacterial infectious disorders

Synonym
early-onset neonatal sepsis, neonatal sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Tergooiziekenhuizen
Source(s) of monetary or material Support: Samenwerkingsverband Pediatrie in Nederland - Nederlandse Vereniging voor Kindergeneeskunde;subsidie via het Prins Bernard

Cultuurfonds

Intervention

Keyword: antibiotic exposure, early-onset sepsis, EOS calculator

Outcome measures

Primary outcome

Co-primary superiority outcome

The proportion of patients starting antibiotic therapy started for suspected and, or proven EOS in the first 24 hours after birth.

Co-primary non-inferiority outcome

The presence of one or more of four predefined safety criteria, namely 1) the need for any respiratory support, and/or 2) the need for an intravascular fluid bolus for hemodynamic instability due to sepsis, and/or 3) referral to a Neonatal Intensive Care Unit for sepsis treatment, and/or 4) proven EOS.

Secondary outcome

Secondary endpoints are:

- The total duration of antibiotic therapy;

- The percentage antibiotic therapy started for suspected and, or proven EOS between 24 hours and 7 days after birth;

- Quality of life: To get an impression of the impact of (suspected) EOS on parents/guardians and their child, parents/guardians will be asked to fill in a questionnaire on day 14.

Study description

Background summary

Newborns are at risk for early-onset sepsis (EOS). A (suspected) EOS is defined as a (suspected) infection that develops within 72 hours after birth. The incidence of confirmed EOS is 0.5-2.0 per 1000 live births. For the Netherlands, this translates to approximately 85-340 EOS cases yearly. However, approximately 5% of late preterm and term newborns are given antibiotics in compliance with current Dutch guideline, which is equivalent to 8,500 newborns per year. An alternative is the CE certified EOS calculator application, an algorithm that divides newborns into risk groups with concrete treatment advice (antibiotics, extra observation, normal care), which calculates an individual risk of EOS for each newborn using 5 maternal risk factors combined with the newborn*s clinical condition after birth. This study aims to investigate whether the use of the EOS calculator safely reduces antibiotic exposure in newborns with suspected EOS compared to the current Dutch guideline.

Study objective

The primary objective of this study is to investigate whether the use of the EOS calculator safely reduces antibiotic exposure in newborns with suspected EOS in the first 24 hours after birth compared to the current Dutch guidelines.

Secondary objectives of the study are:
1. To investigate if the use of the EOS calculator decreases the total duration of antibiotic therapy in newborns with suspected EOS.
2. To investigate if the use of the EOS calculator decreases the percentage of antibiotic therapy started for suspected and, or proven EOS between 24 hours and 7 days after birth.
3. To study the impact of (suspected) EOS on parents/guardians.

Study design

This is prospective, cluster-randomized trial. We aim to include 1830 newborns from 10 hospitals in the Netherlands during an 18-month period. Cluster-randomization happens at the hospital level. A cluster is finished when a total of 183 participants are included into the cluster.

Study burden and risks

This study will have negligible risks and minimal burden.

Burden
- Newborns who receive antibiotic therapy: An intravenous cannula will be

inserted for antibiotic treatment and blood sampling. A second blood sample by venipuncture will be collected after 24 hours. This is part of standard medical treatment.
- Newborns who do not receive antibiotic therapy: No blood samples taken. Clinical observation for at least 24 hours. This is part of standard medical treatment.
- All newborns: One short questionnaire will be sent to the parents/guardians to fulfill on day 14. The questionnaire will take about 10-15 minutes to complete.

Risks:
The risks associated with participation are very low because newborns will be closely observed when no antibiotics will be prescribed.

Benefits
- More specific risk analysis.
- Not all subjects will benefit personally from study participation. When no antibiotics will be prescribed: no separation of mother and child, no painful procedures, and a shorter hospital stay (including fewer costs), and no unnecessary exposure to antibiotics.

Group relatedness
This study can only be performed with this specific group of patients, as it will provide age-specific and risk factor-specific data that cannot be obtained otherwise.

Contacts

Public
Tergooiziekenhuizen

Rijksstraatweg 1
Blaricum 1261 AN
NL
Scientific
Tergooiziekenhuizen

Rijksstraatweg 1
Blaricum 1261 AN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

- postmenstrual age of 34 weeks or more;
- age between 0-24 hours;
- at least one EOS risk factor or clinical sign of infection (suspected of EOS) present within the first 24 hours of life (see Table 1, chapter 3);
- parental consent.

Exclusion criteria

- major congenital anomalies;
- language barrier (lack of effective communication or whenever it hinders understanding).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-04-2022
Enrollment:	1830
Type:	Actual

Medical products/devices used

Generic name:	EOS Calculator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-01-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-11-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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
ClinicalTrials.gov	NCT05274776
CCMO	NL78203.018.21