Procalcitonin as parameter for neonatal infection

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Primary objective:- Determine whether PCT, measured in cord blood, and the blood of the neonate, is suitable to determine the presence or absence of neonatal infection.Secondary objective:- To investigate whether PCT is a suitable parameter to...

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

Summary

ID

NL-OMON49787

Source
ToetsingOnline

Brief title
Pro-EOS study

Condition

- Bacterial infectious disorders

Synonym
infection of the newborn, Perinatal infection

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Gasthuis
Source(s) of monetary or material Support: Spaarne Gasthuis,Thermo Fisher Scientific

Intervention

Keyword: CRP, Infection, Neonate, Procalcitonin

Outcome measures

Primary outcome

The sensitivity and specificity of PCT for infection in the newborn tested in the umbilical cord blood, and in subsequent follow-up measurements in venous blood.

Secondary outcome

- The level of PCT measured in umbilical cord blood.

- The level of PCT and CRP in the blood measured in newborns with a (suspected) infection.

Study description

Background summary

Perinatal infection is one of the most reported causes of child mortality and morbidity worldwide. In order to treat in a fast and save way, adequate diagnostics are major significant to clinical assessment. A range of different parameters have been used so far. At this moment the blood culture is used as the gold standard for establishing the presence of infection. Secondary, C-reactive protein (CRP) also plays an important role in assessing the presence of infection and measuring the severity of it.
Our research will investigate whether procalcitonin (PCT) is a better parameter for determining the presence of infection. The objective of this study is to determine if PCT is suitable for diagnosing the presence/absence of neonatal infection in an early stage. We expect that with the knowledge acquired it is possible to establish in an earlier stage whether it is really necessary to start with antibiotic treatment. The importance of this is great, since antibiotics have a long lasting and significant impact on the microbiome, resulting in later life health complaints such as allergy and obesity.

Study objective

Primary objective:
- Determine whether PCT, measured in cord blood, and the blood of the neonate, is suitable to determine the presence or absence of neonatal infection.

Secondary objective:
- To investigate whether PCT is a suitable parameter to determine the need to start with antibiotic treatment.
- To establish if PCT has a higher sensitivity and specificity for infection compared to CRP.

Study design

The population will consist of neonates born in the Spaarne Gasthuis hospital in Haarlem and the Tergooi hospital in Blaricum. Neonates <7 days old will be included in the study.
In practice, this means inclusion will be from three groups:
1. Neonates with maternal risk factors for infection antenatally
2. Neonates without maternal risk factors antenatally but only with a clinical suspicion for infection established by a peadiatrician.
3. Neonates without a risk factor or a suspicion for infection.

In the first group parents/guardians will be invited to participate in the study if of one or more maternal risk factors for early-onset neonatal infection will be present (as seen in table 2b of the NVK guideline 'prevention and treatment of early-onset neonatal infections*). Parents/guardians will be informed about the possibility to participate both in person and via a patient information brochure. After permission for participation has been given, informed consent will be requested using the consent form. In this group, neonatal umbilical cord blood will be collected postnatally.

It is standard policy to draw blood before starting with antibiotic therapy to determine the complete blood count with differentiation, CRP levels and for preforming a blood culture. The moments blood is drawn from a participating neonate for establishing CRP levels, the leftover blood material will be used for the study. No additional blood tests will take place within the scope of the study. According to the current guideline, one CRP-test is performed at the first suspicion for infection and one after 24-48 hours. The PCT measurements will be linked to this.
Ultimately, the outcomes of the PCT levels, the blood culture, CRP levels, and the complete blood count with differentiation will be used for analysis.

In the second group, newborns of <7 days old without antenatal maternal risk factors for infection, but with a clinical suspicion for infection, will be selected for the study. Like the first group they will also be included in the study starting at the moment they receive antibiotic treatment. The same consent procedure will take place. In this group, leftover blood samples drawn for a clinical CRP measurement will be used to do a later PCT measurement.

In the third group, newborns without risk factors, or suspicion of infection will be included. Specific attention will be paid to the absence of maternal risk factors for early-onset neonatal infection. In this group, neonatal umbilical cord blood will be collected postnatally.

Blood samples from all groups are, for logistical reasons, stored and analyzed in batches. As a result, the attending physician cannot be informed regarding the outcome of the PCT measurement. Once PCT is measured in the blood samples, access to the individual outcomes will be limited to the research team.

During analysis, participating newborns with a negative blood culture will become part of the control group. Newborns with a positive blood culture will be part of the "case group". In this cohort study 5 controls will be included for each case.

PCT levels will be determined by the hospital laboratory of the Spaarne Gasthuis from the (frozen) blood samples of participating patients. The interim results of this study will have no role in the treatment strategy of the participating patients.

In addition, clinical parameters from all participating patients, and their mothers, will be taken from the patient file according to the parameters shown in table 2b and 3b of the NVK guideline. Additionally data regarding, body temperature, blood pressure, capillary refill, respiratory frequency, heart rate, saturation, neurological state, urine output, and medical reasoning for decisions will be collected. All data will be processed in the database in a pseudonymized manner.

Study burden and risks

The PCT level is measured in the umbilical cord blood postnatally. No risk is involved for both mother and child. In case of a suspicion of neonatal infection, blood might be drawn by a paediatrician for a clinical CRP test. If this is the case, the PCT will also be determined from the same blood sample. No additional blood collection is therefore performed. This means that there are no additional risks and burdens attached to this study for the newborn, other than the blood collection already carried out.
Research data will not be shared with the patient's parents/guardian. The treatment is not influenced by the research, unless interim analysis shows that adjustment is desirable. The data will only be analyzed in a pseudonymised manner and parents will be asked to provide informed consent verbally and in writing.

There is no direct benefit for patient or parents if they cooperate with the study. However, they will contribute to a possible improvement of the diagnosis for neonatal infection and the consequent treatment for future patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

• Amenorrhea of >= 32 weeks, age <7 days old
- Neonates that had one or more prenatal risk factors for neonatal infection according to table 2b in the NVK early-onset neonatal infection protocol, OR neonates that are admitted with a suspected infection <7 days postpartum.

Exclusion criteria

• (Suspected) chromosomal abnormalities or severe congenital anomalies.
• Neonates born in an other hospital/neonates who have been admitted to another hospital in the past.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	22-04-2019
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	28-03-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL67266.029.18

Study results

Date completed: 28-03-2021

Results posted: 13-01-2022

First publication
01-01-1900

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