Diagnostic value of soluble CD14 subtype in neonatal sepsis

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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-OMON55522

Source
ToetsingOnline

Brief title
Diagnostic value of soluble CD14 subtype in neonatal sepsis

Condition

- Bacterial infectious disorders
- Neonatal and perinatal conditions

Synonym
bacterial infection, neonatal sepsis

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: Stichting Wetenschap OLVG

Intervention

Keyword: Infant newborn, Neonatal sepsis, soluble CD14 subtype

Outcome measures

Primary outcome

The main study parameter is the difference in plasma sCD14-ST level between infants with and without neonatal sepsis.

Secondary outcome

- the difference in plasma sCD14-ST level over time between infants with and without neonatal sepsis.

- discordance in positive and negative outcomes of molecular blood culturing (IS-pro) compared to outcomes of whole blood culturing between infants with and without neonatal sepsis

- difference in intestinal microbiota composition between infants who received antibiotics less than 72 hours compared to infants who received antibiotics longer than 72 hours.

Study description

Background summary

Early diagnosis is essential in neonatal sepsis as the signs and symptoms are nonspecific. Delays in diagnosis may lead to progressive deterioration. Although blood culture is the gold standard for the diagnosis, false-negative results and long incubation period limits the use of blood culture in neonatal sepsis. To avoid unnecessary treatment of non-infected neonates, an early, sensitive and specific laboratory test would be helpful to guide clinicians in neonatal units to decide whether or not to start antibiotics. Soluble CD14 subtype (sCD14-ST) is a promising candidate biomarker for this purpose. sCD14-ST has high sensitivity and specificity for the diagnosis of neonatal sepsis and is potentially superior to C-reactive protein (CRP) and

procalcitonin (PCT). However, data are limited, and a clear cut-off value with a high negative predictive value is lacking.

Study objective

The aim of this study is to evaluate the diagnostic value of sCD14-ST in the diagnosis of neonatal sepsis. The secondary aim is to evaluate whether serial measurement of sCD14-ST after suspected sepsis onset is of additive predictive value for the diagnosis neonatal sepsis in this vulnerable group.

Study design

Prospective observational cohort study.

Study burden and risks

Participation in the study involves no risks and a minimal burden for the included patients. All included patients are treated based on standard clinical care. No extra punctures are performed for study purposes. In total an extra 1 or 2 mL (dependent on duration of pregnancy) of blood is drawn together with the standard blood tests. No treatment decisions are made based on the plasma levels of sCD14-ST. Additionally, feces samples will be collected at 48 hours, 10 days, 3 and 12 months after birth.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

• Admitted to the Neonatal unit
• Undergoing sepsis evaluation according to the Dutch early onset neonatal sepsis guideline, or local late-onset sepsis guideline.
• Informed consent of parents or legal guardian(s)

Exclusion criteria

• Confirmed intrauterine infection (toxoplasmosis, rubella, cytomegalovirus, syphilis and herpes)

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	30-07-2018
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-05-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-04-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-07-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-10-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-03-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	08-12-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-12-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL61402.100.17