Detection of neonatal sepsis using dynamic light scattering skin sensors

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The primary objective is to determine the difference in median red blood cell velocity (RBV) measured within a time interval of half an hour with dynamic light scattering technology between neonates with and without neonatal late-onset sepsis.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON54452

Source
ToetsingOnline

Brief title
Detection Of Neonatal Sepsis (DONS)

Condition

- Other condition

Synonym
blood poisoning, sepsis

Health condition

neonatale sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Elfi-Tech Ltd., Rehovot, Israel,Health~Holland (topsector Life Sciences & Health)

Intervention

Keyword: dynamic light scattering, microcirculation, neonatal sepsis, red blood cell velocity

Outcome measures

Primary outcome

The main study endpoint is the microcirculatory red blood cell velocity

measured with the dynamic light scattering sensor in neonates during sepsis

compared to neonates in whom sepsis is not proven.

Secondary outcome

Secondary study endpoints include:

- Sensitivity and specificity of measured changes in the microcirculatory blood

velocity and relative blood flow during neonatal sepsis between patients who

develop sepsis and patients in whom sepsis is only suspected

- The correlation between measured changes in the microcirculatory blood

velocity and relative blood flow, and changes in central hemodynamic system

during recovery from neonatal sepsis

- The difference between centrally and peripherally measured blood velocity and

relative blood flow.

- The optimal location for determining changes in the microcirculatory blood

velocity and relative blood flow during neonatal sepsis

- The accuracy of the heart rate measured with dynamic light scattering

- The calculation of the cardiac output from the pulsatile flow waveform

- The relation between heart rate variability changes and changes in

microcirculatory blood velocity and relative blood flow.

- The effect of inotropic administration, or other clinical interventions, on

microcirculatory blood velocity and relative blood flow.

- Peak detection and beat-to-beat analysis for the detection of measurement

errors and signal disturbances

Study description

Background summary

Current hemodynamic monitoring in the neonatal intensive care unit (NICU) is focused on the central systemic circulation. It is however known that the microcirculation is one of the systems which are affected already in the early phase of certain diseases, such as late-onset sepsis. The microcirculation could therefore be an important indicator of the severity of sepsis and the response to therapy. Currently there is no continuous clinical parameter which indicates the microcirculatory state. Recently, a new miniaturised dynamic light scattering (DLS) sensor has become available which enables measurement of the microcirculatory blood velocity. We hypothesise that with this measurement technology, differences in microcirculatory blood velocity can be found between septic neonates and neonates in whom a suspicion of sepsis is not proven.

Study objective

The primary objective is to determine the difference in median red blood cell velocity (RBV) measured within a time interval of half an hour with dynamic light scattering technology between neonates with and without neonatal late-onset sepsis.

Study design

This pilot study is a prospective observational cohort study. When neonatal (late-onset) sepsis is suspected and informed consent is obtained, blood velocity measurements using one or two dynamic light scattering sensors will be performed. Blood velocity measurements will be continued until cessation of antibiotic treatment.

Study burden and risks

The sensor will be attached to the skin using double- sided adhesives, custom adhesive rings and/or commercially available adhesive rings that are used for regular care transcutaneous blood gas monitoring. With these adhesives, the sensors can be kept in place for several days. The DLS sensor contains a class 1 laser source and is safe for the human retina. Several studies have shown these lasers to be safe for the neonatal retina in particular. As preterm neonates still develop the ability to focus their eyes, they have a much smaller effective capacity to focus which is the main reason that the intensity of the DLS laser will be substantially less in premature neonates. Moreover, class 1 lasers are characterised to cause no thermal effects on the retinal tissue when fully focussed on the retina, regardless of the exposure time. Both the suboptimal capacity of focusing in preterm neonates and the use of a class 1 laser, lead to no additional risk of the DLS laser in preterm neonates.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Babies and toddlers (28 days-23 months)
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

- Suspicion of late-onset sepsis
- Written informed consent of parents or guardian
- Blood culture is drawn

Exclusion criteria

- Skin disorder (including frailty of the skin) for which the skin adhesive is contraindicated

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-05-2022
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	30-04-2021
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-10-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL75470.078.20