Seroepidemiological Longitudinal RSV-specific Antibodies Transfer Study

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

Summary

ID

NL-OMON53767

Source
ToetsingOnline

Brief title
SILVER

Condition

- Other condition
- Viral infectious disorders

Synonym
early term neonate

Health condition

prematuriteit

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Pfizer

Intervention

Keyword: antibody transfer, half-life, maternally acquired, prematurity, RSV

Outcome measures

Primary outcome

1. To measure maternal naturally occurring neutralizing RSV antibody levels at birth as function of gestational age, and

2. To quantify transplacental antibody transfer ratios of RSV-specific antibodies in preterm babies depending on their gestational age group and compared to ratios obtained in term neonates

Secondary outcome

1. SILVER describes post-partum half-life of maternally acquired RSV-specific antibodies in preterm and full-term neonates. Preterm and full-term neonates will be followed up after birth to capture the decrease in maternally acquired RSV-specific antibodies in their first weeks of life. The SILVER study will describe the half-life of maternally acquired RSV-specific antibodies in neonates in relation to their gestational age, repeated blood-draws during hospitalization and health status and comorbidities.

2. SILVER will describe the health of the placenta in relation to antibody transfer.

3. SILVER will describe the correlation between RSV seasonality (using local

public health surveillance data from RIVM) and observed antibodies of

pregnant woman.

Study description

Background summary

Respiratory syncytial virus (RSV) infection is an important cause of hospitalization and death in children younger than 5 years. A vaccine against RSV infection is expected to become available in the next 5-10 years. Next to the degree to which a vaccine will boost levels of maternal protective antibodies and the degree to which these RSV antibodies are transported trans-placental to the foetus, the success of a maternal RSV vaccination strategy will also be defined by the half-life of vaccine-induced maternally acquired antibodies after birth.
Given the complex health conditions of premature babies including, but not limited to repeated blood-draws during their hospitalization, it is conceivable that there is a more rapid decrease of antibodies during this period of time leading to increased risk of RSV infection.

Study objective

The SILVER study aims to give insight into the half-life of maternally acquired antibodies in preterms and the foetus to mother transfer function. These findings have implications for understanding infectious disease susceptibility, vaccine development, and vaccine scheduling in premature neonates.

Study design

SILVER is a cross-sectional prospective seroepidemiologic study. At birth neonatal blood specimen from both pre-term and term neonates as well as maternal blood sample will be scavenged from standard of care specimens and/or by taking additional capillary blood samples, in addition to a the collection of placental specimens. We will collect clinical and demographical characteristics of the mother and foetus pairs to use as covariates in our model. In the second part, the babies will be followed-up up to 8 weeks to measure antibody level decrease.

Study burden and risks

Risks and burdens for study subjects are considered to be minimal. No safety issues are expected due to the set-up and nature of the study.

There are no direct or indirect benefits for the participants. Burden for the participant is minimal, as only a small amount of blood volume is required and the sampling can be performed quickly and easily.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Babies and toddlers (28 days-23 months)
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

1. Women >=18 years of age and pregnant.
2. Woman with hospitalization at the WKZ hospital due to imminent labor from 240/7 weeks of gestation.
3. Both parent(s)/legal guardian(s) must be willing to adhere to the protocol and sign informed consent. A signature from the mother is sufficient in case

consent from the father cannot be obtained.
4. The maternal participant must be willing to accept maternal blood specimen collection and neonate specimens collection and relevant clinical and medical history data collection.

Exclusion criteria

There are no exclusion criteria for the study. If mothers have a medical diagnosis or pregnancy-related condition that is suspected to impact the transplacental transfer rate, these confounding variables (comorbidities) will be documented and accounted for in the analyses.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2022
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	24-02-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	15-09-2023

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-01-2024
Application type:	Amendment
Review commission:	METC NedMec

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	NL79793.041.21