Optimizing primary vaccination schedule for premature infants

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Primary Objectives:1) To determine immunogenicity of NIP vaccines in preterm infants when vaccinated according to the current Dutch NIP schedule and with rotavirus vaccine following the RIVAR study.2) To unravel the mechanism of immature host...

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

Summary

ID

NL-OMON44869

Source
ToetsingOnline

Brief title
PRIEMA study

Condition

- Other condition
- Hepatobiliary neoplasms malignant and unspecified

Synonym
antibody's, immunogenicity

Health condition

immunogeniciteit bij prematuren ten aanzien van respons op de vaccinaties uit het RVP en de rotavirusvaccinatie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: vrijwillige RIVM grant ten behoeve uitvoer van de PRIEMA studie

Intervention

Keyword: antibody levels, preterm infants, vaccination

Outcome measures

Primary outcome

Main study parameter/endpoint

* Antibody levels against the regular NIP vaccine components (DTaP, IPV, HIb,

HepB and PCV10) at 5 and 12 month of age in preterm infants.

Secondary outcome

Secondary study parameters/endpoints

* Levels of maternal antibodies at 6 weeks of age

* Cellular immunity at 12 month

* Timelines of NIP vaccines

* Tolerability and vaccine side effects

* Rotavirus seroconversion rates and antibody levels at 5 an 12 month of age

among those vaccinated

Study description

Background summary

The National Immunization Program (NIP) aims to protect all individuals and the population at large against the target diseases. The current *one size fits all* NIP schedule may not provide optimal protection to preterm infants, a situation that is highly undesirable, both from a societal perspective, because

of the negative impact on herd-immunity, and for reasons of individual health risks with infection in this vulnerable population. A targeted and personalized approach to vaccination of the 15.000 preterm infants born annually, could improve overall NIP effectiveness. Yet, optimal timing and dosing for this group is currently unknown. Immunogenicity studies in preterm infants and clinical testing of alternative vaccination schedules is critical to optimize their protection against vaccine preventable diseases.

Study objective

Primary Objectives:
1) To determine immunogenicity of NIP vaccines in preterm infants when vaccinated according to the current Dutch NIP schedule and with rotavirus vaccine following the RIVAR study.
2) To unravel the mechanism of immature host responses and interaction with gestational age (GA)
3) To propose alternative, better-adapted vaccination schedules with respect to number and timing of doses for preterm infants, based on the immunogenicity findings

Secondary Objective(s):
1) To determine the tolerability of NIP vaccines and rotavirus vaccine in preterm infants as measured by the occurrence of vaccine side effects.
2) To determine the timelines of NIP vaccines in preterm infants under the current NIP schedule.
3) To explore the possible cellular immune mechanisms for the impaired vaccine response in preterm infants
4) To explore possible immunological differences between preterm infants delivered by caesarion section or by natural vaginal delivery and between breath fed versus formula fed infants.

Study design

Observational study nested within the non- WMO RIVAR (Risk-group Infant Vaccination Against Rotavirus) study. All RIVAR participants are eligible for inclusion. PRIEMA participants will undergo blood sampling.

Study burden and risks

The PRIEMA study can only be performed in preterm infants.
Blood sampling from infants participating in the immunogenicity study will be performed by venapuncture and combined with routine medically indicated blood sampling whenever possible. In all other circumstances a trained research nurse or medical doctor will perform venapuncture during routine clinic or study home-visits. Analgestic cream will be locally applied to the infants skin prior to the procedure. A maximum of two attempts to collect blood will be executed

per scheduled measurement time-point. The procedure of blood sampling by venapuncture is of extremely low risk to the infant and of minimal discomfort. The stool samples collected by parents of participating infants will be taken from soiled diapers and are therefore non-invasive. Checking the dates of vaccinations and weight from the "green book", will not take more then 5 minutes.
Therefore, the risk and burden of participation in this study are minimal as compared to the potential value of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

preterm infants, stratified in 3 groups (<28 weeks, 28-32 weeks or 32-36 weeks GA), included via RIVAR study

Exclusion criteria

not willing to let take blood

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2015
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	04-09-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-10-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	30-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL52368.041.15

Study results

Date completed:	19-11-2018
Actual enrolment:	298