Optimizing primary vaccination schedule for premature infants

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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. To unravel the mechanism of immature host responses and interaction...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21928

Bron
NTR

Verkorte titel
PRIEMA

Aandoening

National immunization program (NIP), preterm infants, immune response

Ondersteuning

Primaire sponsor: Rijksinstituut voor Volksgezondheid en Milieu (RIVM)
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Overige ondersteuning: Rijksinstituut voor Volksgezondheid en Milieu (RIVM)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Seroconversion rates at 5 and 12 months of age in preterm infants and absolute antibody levels against the regular NIP vaccine components (DTaP, IPV, HIb, HepB and PCV10.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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.

Objective: 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)
Study design: : Observational study nested within the non- WMO RIVAR (Risk-group Infant Vaccination Against Rotavirus) study. PRIEMA participants will undergo blood sampling.

Study population: Preterm infants included in RIVAR study. There will be three groups:

32-36, 28-32 and <28 weeks GA.

Main study parameters/endpoints: Antibody levels against the regular NIP vaccine components (DTaP, IPV, HIb, HepB and PCV10) at 5 and 12 month of age in preterm infants.

Nature and extent of the burden and risks associated with participation, benefit and group

relatedness:

The PRIEMA study can therefore only be performed in the target-group i.e. preterm infants.

Blood sampling from infants participating in the PRIEMA sub-study, nested within the RIVAR 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. Analgesic cream will be locally applied to the infants skin, in consultation with the parents, 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. Additional data collection includes double-checking of vaccination dates, already collected through questionnaires, according to “the green book” of the child.

Doel van het onderzoek

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.

To unravel the mechanism of immature host responses and interaction with gestational age (GA)

Onderzoeksopzet

Blood samples will be taken at age of 6 weeks, 5 and 12 months. Blood sampling has to be done after the standard NIP vaccinations are given, except for the sample at 6 weeks.

- At the same time-point a stool sample will be taken

Onderzoeksproduct en/of interventie

No interventions. This is an observational study on immune respons after vaccination in preterm infants according to the current NIP schedule.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Eligible for RIVAR study (This study is nested within an observational step-wedged cohort non-WMO study,RIVAR)

- Preterm infant (36 weeks of gestational age or younger).-

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Not willing to take part in blood sampling

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-10-2015
Aantal proefpersonen:	300
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	19-06-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7142
NTR-old	NTR7340
Ander register	METC : 15-399/M

Resultaten