Premature infants and maternal pertussis immunization. Is second trimester vaccination beneficial?

Gepubliceerd: 05-11-2018 Laatst bijgewerkt: 19-03-2025

Non-inferiority of anti-Pertussis Toxin (PT) IgG in term infants at 2m of age born of mothers having received a pertussis vaccine between 20-24w Gestational Age (GA) compared to a reference anti-PT IgG at 2m of age in a historical control group of...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21026

Bron
Nationaal Trial Register

Verkorte titel
PIMPI-study

Aandoening

maternal vaccination; pertussis; premature; preterm infants

Ondersteuning

Primaire sponsor: RIVM, UMCU
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Serum IgG antibody levels against vaccine antigen PT in preterm and term infants at 2 months of age, before start of infant vaccination

Toelichting onderzoek

Achtergrond van het onderzoek

Data have shown that 3rd trimester is 91% effective in preventing pertussis in young infants and 95% effective in preventing death due to pertussis. However, data also show that preterm infants profit less form 3rd trimester pertussis vaccination, probably due to insufficient time for antibody transfer. In this prospective cohort study, our primary objective is to evaluate non-inferiority of anti-pertussis toxin IgG in term and preterm infants at 2m of age born of mothers having received a pertussis vaccine between 20-24w gestational age, compared to a historical control group of term and preterm infants born of mothers who were vaccinated between 30-32w gestational age.

Doel van het onderzoek

Non-inferiority of anti-Pertussis Toxin (PT) IgG in term infants at 2m of age born of mothers having received a pertussis vaccine between 20-24w Gestational Age (GA) compared to a reference anti-PT IgG at 2m of age in a historical control group of term infants born of mothers who were vaccinated between 30-32w GA. Likewise, we expect non-inferiotiry of anti-PT IgG in preterm infants at 2m of age born of mothers having received a pertussis vaccine between 20-24w GA compared to the 20 IU/ml anti-PT IgG cut-off used in many immunogenicity studies

Onderzoeksopzet

20-24w gestational age, birth, 2 months after delivery

Onderzoeksproduct en/of interventie

maternal pertussis vaccine between 20-24 weeks gestational age

Contactpersonen

Publiek

RIVM - UMCU
Maarten Immink

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Wetenschappelijk

RIVM - UMCU
Maarten Immink

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

18 years or older; being pregnant; having an antenatal appointment with a midwife or obstetrician in the 1st trimester of pregnancy; parents who are willing to adhere to the protocol and perform all planned visits and sample collections for themselves and their newborn child.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

History of having received a pertussis containing vaccination in the past 2 years; history of having had pertussis disease in the past 5 years; known or suspected serious underlying condition that can interfere with the results of the study such as but not limited to cancer, autoimmune disease, immunodeficiency, seizure disorder or significant psychiatric illness; receipt of any high-dose daily corticosteroids within 2 weeks of study entry with exception of corticosteroids to enhance maturation of fetal lungs in case of imminent early delivery; receipt of other immune modulation medication, for instance biologicals; receipt of blood products or immunoglobulins within three months of study entry; bleeding disorder; having experienced a previous severe adverse reaction to any vaccine; receipt of any vaccine(s) within 2 weeks of study vaccine (except influenza vaccine).

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	6750
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	05-11-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49737
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7403
NTR-old	NTR7619
CCMO	NL66966.000.18
OMON	NL-OMON49737

Resultaten