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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21026

Source
Nationaal Trial Register

Brief title
PIMPI-study

Health condition

maternal vaccination; pertussis; premature; preterm infants

Sponsors and support

Primary sponsor: RIVM, UMCU
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Anti-Pertissis toxin (PT), pertacin (Prn), filamentous hemagglutinin (FHA) concentrations, tetanus or diphteria in the mother at delivery, in the infant at birth (cord blood) or at 2m of age. Decay in anti-PT, Prn, FHA, tetanus and diphteria in infants from birth at 2m of months of age. Ratio between GMCs and GMCs at birth. Frequency in systemic (adverse) events occuring within 7 days before or 7 days after vaccination vaccination. Frequency of determinants of acceptance of 2nd trimester pertussis vaccination. Determinants of women's attitude towards maternal pertussis vaccination between 20-24w GA.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

maternal pertussis vaccine between 20-24 weeks gestational age

Contacts

Public
RIVM - UMCU
Maarten Immink

0631939134
Scientific
RIVM - UMCU
Maarten Immink

0631939134

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2019
Enrollment:	6750
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	05-11-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49737
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results