Immunisation of pregnant women with acellular Bordetella pertussis vaccine.

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1) To test the feasibility of vaccinating pregnant women against B. pertussis in preventing B. pertussis infection in newborn babies.2) To test the safety of vaccinating pregnant women against B. pertussis in preventing B. pertussis infection in...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON33816

Source
ToetsingOnline

Brief title
Bordetella pertussis vaccination in pregnancy

Condition

- Bacterial infectious disorders
- Neonatal and perinatal conditions

Synonym
whooping cough

Research involving
Human

Sponsors and support

Primary sponsor: Groene Hart Ziekenhuis
Source(s) of monetary or material Support: subsidies worden aangevraagd;vaccins gratis terbeschikking gesteld door fabrikant

Intervention

Keyword: immunization, pertussis, pregnangy, vaccination

Outcome measures

Primary outcome

1. Feasibility:

a. Part 1. Determination of pertussis specific antibody responses and persistence in mother and child after vaccination of the mother during pregnancy. Antibody titres of women vaccinated during pregnancy will be measured and compared with data from an ongoing study on titres in pregnant women not vaccinated during the study and with data on titres of pregnant women who have recently been infected with B. pertussis.

b. Part 2. Determination of transplacental transfer of different antibodies against B. pertussis and the decline of these antibodies in the infant post natal.

2. Safety:

a. Part 1. Rate of adverse events in pregnant women after immunization (using the WHO criteria).

b. Part 2. Rate of adverse events after immunization in infants of vaccinated

mothers.

Secondary outcome

1. The number of infections with B. pertussis in infants and mothers after

maternal vaccination until the first year after birth.

2. The course of antibody-titers in infants of vaccinated mothers will be

studied before and after routine childhood vaccination.

3. Antibody-titers to diphtheria, tetanus and polio will be measured.

Study description

Background summary

Bordetella pertussis, the causative agent of whooping cough, can cause severe disease in infants too young to be vaccinated or who have not completed the primary series. In complete vaccination, 100% protection is reached after 4 to 5 months (1).
Despite vaccination the incidence of whooping cough is rising the last decade with the highest infection-frequency in adolescents and young adults. The latter can be an important source of infection to infants less than 4 to 5 months old. Maternal immunization offers the possibility to protect these infants from birth until immunity is achieved by active vaccination this has proven to be effective in tetanus and influenza. Several studies indicated that maternal immunization against B. pertussis may be effective (2). For the development of a vaccination programme against B. pertussis in pregnant women knowledge is needed about the antibody-response in mother and child after maternal vaccination.

Study objective

1) To test the feasibility of vaccinating pregnant women against B. pertussis in preventing B. pertussis infection in newborn babies.
2) To test the safety of vaccinating pregnant women against B. pertussis in preventing B. pertussis infection in newborn babies.

Study design

A prospective cohort study.
Part 1: Immunization of pregnant women in the third trimester of pregnancy with

an acellular pertussis vaccine. Blood samples will be drawn to study antibody responses.

Part 2: Blood samples of infants of mothers vaccinated during pregnancy in part 1 will be drawn to study antibody responses.

Intervention

The study group will receive an DTaP-IPV booster vaccine, with reduced D and monovalent aP content vaccine during the third trimester of pregnancy.

Study burden and risks

Pregnant women are vaccinated with an acellular vaccine, intramuscularly, during the third trimester of pregnancy by an experienced nurse. Blood samples will be taken before vaccination, at delivery and at 2 months post-partum. Participants will be visited for all blood sampling by experienced study nurses at home to minimize distress. A questionnaire will be handed out to these women to gain insight in previous immunization and suspected whooping cough.
From infants of mothers included in the study blood will be drawn from the umbilical cord at delivery and by capillary heel prick tests at 2 month post partum (before their first vaccination) and 1 month after the 1st, 3rd and 4th vaccination (vaccinations at 2,3,4 and 11 months). These capillary tests are less invasive than venous blood sampling.
Based on an extensive literature review (3-8) the estimated risk for the participants in this study is minimal.

Side-effects that were associated with vigorous serum antibody responses are: pain, tenderness, induration or erythema at the site of injection (18).
According to recommendations of the US Advisory Committee on immunization practices (ACIP), pregnancy is not a contraindication for vaccination with adult formulations of a combined tetanus, diphtheria, acellular pertussis vaccine. Data on safety, immunogenicity and the outcomes of pregnancy are not available for pregnant women who receive Tdap. When Tdap is administered during pregnancy, transplacental maternal antibodies might protect the infant against pertussis in early life. They also could interfere with the infant's immune response to infant doses of DTaP, and leave the infant less well protected against pertussis (9).

The risk and the burden for the subject will be in proportion to the potential value of the research because we expect that vaccinating pregnant women will provide protection against B. Pertussis in the neonate directly from birth on. Hence, complicated infections with B. Pertussis will be prevented.

3) Mooi FR, de Greeff SC. The case for maternal vaccination against pertussis.

Lancet Infect Dis. 2007 ;7:614-624
4) Glezen WP, Alpers M. Maternal immunization. Clin Infect Dis:1999;219-224
5) Kendrick P, Thompson M, Eldering G. Immunity response of mothers and babies to injections of pertussis vaccine during pregnancy. Am J Dis Childr 1945;70;25-8
6) Lichty JA, Slavin V, Bradford WL. An attempt to increase resistance to pertussis in newborn infants by immunizing their mothers during pregnancy. J Clin Invest 1938;17:613-21
7) Cohen P, Scaldron SJ. The placental transmission of protective antibodies against whooping cough by inoculation of the pregnant women. JAMA 1943;121:656-662
8) Cohen P, Scaldron SJ. The effects of active immunization of the mother upon the offspring. J Pediatr 1946;29:609-19.
9) http://www.cdc.gov/vaccines/pubs/preg-guide.htm#tdap

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

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Exclusion criteria

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Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-07-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2008-005285-31-NL
CCMO	NL23313.000.08