Juveniele Immunisatie Meningokokken ACWY 2 studie

No registrations found.

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

Summary

ID

NL-OMON26652

Source
Nationaal Trial Register

Brief title
JIM2-study

Health condition

MenACWY conjugate vaccination, meningitis, infectious diseases

Sponsors and support

Primary sponsor: National Institute for Public Health and Environment (RIVM)
Source(s) of monetary or material Support: National Institute for Public Health and Environment (RIVM, Bilthoven, The Netherlands)

Intervention

Outcome measures

Primary outcome

The primary objective is to explore the duration of SBA levels for protection (≥8 = persistence of vaccine induced protective antibody levels) and determine the decay rate of SBA levels 5 years after a MenACWY-TT vaccine was administered at the age of 10, 12 or 15 respectively.

Secondary outcome

- To compare SBA levels against MenA, MenC, MenW and MenY of ≥8 between the three age groups at 5 years (T1) after a MenACWY-TT vaccine was administered.
- To compare serum MenA-PS, MenY-PS and MenW-PS specific IgG levels between the three age groups at 5 years (T1) after a MenACWY-TT vaccine was administered.
- To compare serum IgG antibody levels against tetanus, the carrier protein for the vaccine, between the three age groups at 5 years (T1) after a MenACWY-TT vaccine was administered.
- To compare serum IgA levels against MenA, MenC, MenW and MenY between the three age groups at 5 years (T1) after a MenACWY-TT vaccine was administered.
- To compare MenA-PS specific, MenC-PS specific, MenW-PS specific and MenY-PS specific IgG subclasses (IgG1/IgG2 ratio) and avidity within the three age groups at 5 years (T1) after a MenACWY-TT vaccine was administered.

Study description

Background summary

Neisseria meningitidis is a gram-negative diplococcal bacterium and is normally a commensal bacterium in the nasopharynx. However, it can be a devastating pathogen when it enters the blood stream causing invasive meningococcal disease. Different serogroups are distributed geographically around the world, with an increase of serogroup W recently in different countries in Europe, including the Netherlands. In 2018, a tetravalent meningococcal serogroup ACWY tetanus toxoid conjugate vaccine (MenACWY-TT) was therefore introduced in the Dutch National Immunization Program (NIP) to replace the monovalent MenCC vaccine at 14 months of age. In addition a second vaccination at 14 years of age was implemented and a catch-up campaign focussing on teenagers from 14-18 years has started and is still ongoing. Duration of protection after vaccination appears to be age-dependent. It is has been shown that a single vaccination at 14 months is not sufficient to sustain immunity against MenACWY and the need for a second vaccination during adolescence has been acknowledged. A second (booster) vaccination protects adolescents directly and maintains the herd immunity that persists up until today. For meningococcus serogroup C (MenC) it is known that protection is long lasting after a primary vaccination followed by a booster vaccination at an older age. It is crucial to monitor the duration of protection of a MenACWY-TT conjugate vaccine in adolescence after priming with MenC-TT at age of 14 months. However, studies evaluating the long-term persistence of antibodies after the MenACWY-TT vaccine for a second meningococcal vaccination in teenagers and adolescents are lacking.

The aim of this study is to investigate the long-term immune response and determine the persistence of functional antibodies to the tetravalent MenACWY-TT vaccine administered as a second meningococcal vaccination after 5 years. This study will generate important data about the duration of protection after vaccination.

Study objective

The aim of this study is to investigate the long-term follow-up immune response to a tetravalent MenACWY-TT conjugate in participants who were primed with the monovalent MenC-TT conjugate vaccine at a young age and who received the second vaccination 5 years ago when they were aged 10, 12 or 15 years respectively. The study will investigate the persistence of functional antibodies and thus the level of protection 5 years after a tetravalent MenACWY-TT conjugate vaccine.
As a result, this study will provide important information about the duration of protection in the whole population in The Netherlands after the booster vaccination at 14 years of age that was recently implemented in the national immunization program.

Study design

T1: single blood sample, 5 years after MenACWY vaccination

Intervention

A single blood sample will be drawn 5 years after vaccination

Contacts

Public
RIVM
Milou Ohm

0302744246
Scientific
RIVM
Milou Ohm

0302744246

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: participants from the JIM-study were 10, 12 or 15 years old at time of vaccination with a MenACWY-TT vaccine after they received a primary vaccination with a single dose of MenC-TT vaccine (NeisVac-CTM) either during the mass catch-up campaign in 2002 (group 3)

or at the age of 14 months according to the Dutch NIP (group 1, 2 or 3). Furthermore, in order to be eligible to participate in this study, a participant must meet all of the following criteria:
- Provision of written informed consent by the participant and, if the participant is under 16, also by its parent(s) or caregiver(s)
- Good general health
- Received all regular vaccines according to the Dutch NIP
- Adherent to protocol, and available during the study period

Exclusion criteria

Any of the following criteria at the start of the study will exclude a potential subject from participation in this study:
- Previous administration of plasma products (including immunoglobulins) within the last 6 months;
- Pregnancy;
- Previous confirmed or suspected meningococcal disease;
- Received any vaccination in the past month;
- Former received tetravalent MenACWY vaccination administered not as part of the JIM-study
- Known or suspected immune deficiency;
- History of any neurologic disorder, including epilepsy;
- Present evidence of serious disease(s) demanding (immunosuppressive) medical treatment that might interfere with the results of the study within the last 3 months (like corticosteroids, chronic infection, bleeding disorder, immune dysfunction, or genetic anomaly).
In the JIM-study, in addition, any of the following criteria excluded a potential subject from participation in the study:
- Severe acute (infectious) illness or fever (>38.5°C) within 14 days before vaccination;
- Antibiotic use within 14 days of enrollment;
- Known or suspected allergy to any of the vaccine components (by medical history);
- Occurrence of serious adverse event after primary MenC-TT vaccination or other vaccination (by medical history)
- Former received doses of MenC vaccines in addition to the primary vaccination;
- Former received any tetravalent MenACWY vaccination;
NL68774.100.19 / IIV-401 JIM2-study
Version number: 2 April 15, 2019 14 of 27
The participants included in the JIM-study did not meet these exclusion criteria at time of the JIM-study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2019
Enrollment:	221
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-05-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48391
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7735
CCMO	NL68774.100.19
OMON	NL-OMON48391

Study results