Second meningococcal vaccination in Dutch children: Study to compare the tetravalent MenACWY-TT conjugate vaccine with the monovalent MenC-TT conjugate vaccine.

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The aim of this study is to investigate the immune response to a tetravalent MenACWY-TT vaccine in 10-, 12- and 15-year old children primed with the monovalent MenC-TT conjugate vaccine at a young age and to1. determine whether the MenC-specific...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON38656

Source
ToetsingOnline

Brief title
JIM study

Condition

- Bacterial infectious disorders

Synonym
C, Second vaccination against meningococcal A, W and Y disease

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: C, Meningococcus A, second, teenagers, vaccine, W and Y

Outcome measures

Primary outcome

The primary objective is to demonstrate non-inferiority of SBA levels against MenC at 1 year (T2) after vaccination in the group vaccinated with tetravalent MenACWY-TT vaccine as compared with the group vaccinated with monovalent MenC-TT conjugate vaccine in 10-, 12-, and 15-years old children.

If non-inferiority is demonstrated, the objective is to compare SBA levels against MenA, MenW and MenY at 1 year (T2) after vaccination between the three age groups that are vaccinated with tetravalent MenACWY-TT vaccine.

Secondary outcome

- To compare SBA levels against MenC at 1 month (T1) between the vaccine groups within the three age groups.

- To compare SBA levels against MenC of >=8 (persistence of vaccine induced protective antibody levels) at 1 month (T1) and 1 year (T2) between the vaccine groups within the three age groups.

- To compare serum MenC-PS specific IgG levels at 1 month (T1) and 1 year (T2)

between the

vaccine groups within the three age groups.

- To compare the decay rate of SBA levels and MenC-PS specific IgG levels after

secondary

vaccination (i.e. the difference between T2 and T1) between the

vaccine groups within the

three age groups.

- To compare SBA levels against MenA, MenW and MenY at 1 month (T1) between the

three

age groups within the MenACWY-TT vaccine group.

- To compare SBA levels against MenA, MenW and MenY of >=8 at 1 month (T1) and 1

year

(T2) between the three age groups within the MenACWY-TT vaccine group.

- To compare serum MenA-PS, MenY-PS and MenW-PS specific IgG levels at 1 month

(T1)

and 1 year (T2) between the three age groups within the MenACWY-TT

vaccine group.

- To compare serum IgG antibody levels against tetanus, the carrier protein for

both vaccines, at

1 month (T1) and 1 year (T2)? between the vaccine groups within the

three age groups.

- To compare serum IgA levels against MenA, MenC, MenW and MenY at 1 month (T1)

and at

1 year (T2) between the vaccine groups within the three age groups.

- To compare MenC-PS specific IgG subclasses (IgG1/IgG2 ratio) and avidity at 1

month (T1) and 1 year (T2)? between the vaccine groups within the

three age groups.

- To compare SBA and IgG levels against MenC at 1 month and 1 year between the

MenC-TT

group of the current study and the TIM-study for the the 12- and 15-

year olds, to establish the

effect of the age at priming on antibody responses to a second MenC-TT

vaccination during

adolescence.

Study description

Background summary

Neisseria meningitides is a gram-negative diplococcal bacterium that causes septicemia and meningitis. An increase in the relative proportion and the absolute numbers of Meningococcen serogroup C (MenC) invasive meningococcal disease during the 1990s led to the development and routine use of conjugate vaccines. In 2002 a Meningococcal serogroup C conjugated (MenC-TT) vaccination was implemented into the Dutch National Immunization Programme (NIP) for all children aged 14 months.
Meningococcal disease occurs comprehensively world-wide. The different serogroups are geographically distributed around the world. Nowadays, many young adults go travelling world-wide. In the Netherlands, some of these young travelers get already a tetravalent MenACWY-TT vaccine.
The incidence of meningococcen serogroup Y (MenY) appears to increase throughout countries in Europe, including the Netherlands. In the Netherlands, MenY accounted for 12% of invasive meningococcal disease cases in 2012, an increase from 2% in 2006. Therefore, when the incidence of invasive MenY disease in Europa continues to increase, it can lead to serious public health problems.
In the past years it has become clear that protection induced by a primary MenC-TT vaccination appears to be age-dependent. This suggest that without a second vaccination against meninigococci at an older age, children vaccinated

at 14 months will reach the second period of increased risk for invasive meningococcal disease withk low serologic markers of protective immunity. In conclusion, with an increasing incidence of MenY and increasing number of travellelers among the young population , the use of a tetravalent MenACWY-TT vaccine may be beneficial for the second vaccination at an older age in the future. Especially for those vaccinated only once at 14 months of age, to protect the adolescents and maintain the herds community effect that persists up until today.

Study objective

The aim of this study is to investigate the immune response to a tetravalent MenACWY-TT vaccine in 10-, 12- and 15-year old children primed with the monovalent MenC-TT conjugate vaccine at a young age and to
1. determine whether the MenC-specific antibody response after vaccination with a tetravalent MenACWY-TT vaccine is not inferior to MenC specific antibody responses after vaccination with the monovalent MenC-TT conjugate vaccine.
2. determine whether there is an age-dependent difference in the primary response to MenA, MenW and MenY after vaccination with the tetravalent vaccine, as was previously found for MenC.
3. determine the appropriate age for a tetravalent MenACWY-TT conjugate vaccination after priming with MenC-TT at young age.

Study design

Intervention study.

Intervention

Participants will receive the vaccination with either the registered tetravalent vaccine (Nimenrix; 0,5mL) or the registered monovalent (NeisVac-C*; 0,5 mL) at the first visit. Blood and saliva samples will be drawn prior to the vaccination (T0), 1 month (T1) and 1 year (T2) after the vaccination.

Study burden and risks

Participants benefit from participating in the study by receiving an additional MenACWY-TT or MenCC-TT vaccination. From the public health perspective, participation in this study will contribute to the improvement of the National Immunisation Programme (NIP). Vaccination and venapunctures might be painful and unpleasant. On request of the participant, Xylocainespray can be used to reduce possible local pain during the venapunction. Nimenrix and NeisVac-C* are registered vaccinations in the Netherlands. Mild adverse reactions to the vaccine may occur but they are expected to be mainly local and transient. Severe allergic reactions to one of the vaccine components are unlikely to occur. As a compensation for the vaccination and the venapunctures, all

participants will receive a total of ¤25,- in vouchers.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Participants are 10-, 12, and 15-year old children who have received a primary vaccination with a single dose of MenC-PS conjugated (MenC-TT) vaccine NeisVac-C* either during the mass catch-up campaign in 2002 (group 4 and 5) or at the age of 14 months (regular vaccination time point since 2002 according to the Dutch NIP; group 1,2 and 3).
Furthermore, participants have to fulfil all of the following criteria:
- Provision of written informed consent by both parents and (if child is 12 or 15 years old; see Annex 3) child
- Good general health

- Received all regular vaccines according to 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 volunteering child from participation:
- Severe acute (infectious) illness or fever (>38.5°C) within 14 days before vaccination;
- Antibiotic use within 14 days of enrollment;
- Present evidence of serious disease(s) demanding (immunosuppressive) medical treatment that might interfere the results of the study within the last 3 months (like corticosteroids, chronic infection, bleeding disorder, immune dysfunction, genetic anomaly);
- 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)
- Known or suspected immune deficiency;
- History of any neurologic disorder, including epilepsy;
- Previous administration of plasma products (including immunoglobulins) within the last 6 months;
- Pregnancy.
- Previous confirmed or suspected meningococcal disease.
- Former received doses of MenC vaccines in addition to the primary vaccination
- Former received a tetravalent MenACWY vaccine
- Received vaccination in the past month

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-03-2014
Enrollment:	410
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NeisVac-C
Product type:	Medicine
Brand name:	Nimenrix

Ethics review

Approved WMO Date:	01-08-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-08-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-04-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 19891
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-001823-38-NL
CCMO	NL44863.100.13
OMON	NL-OMON19891

Study results

Date completed: 12-05-2015

Actual enrolment: 410