Juveniele Immunisatie Meningokokken ACWY studie

No registrations found.

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

Summary

ID

NL-OMON19891

Source
NTR

Brief title
JIM-studie

Health condition

Second Meningococcal Vaccination
MenC-TT conjugate vaccine
MenACWY-TT conjugate vaccine
Dutch children

Sponsors and support

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

Intervention

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 ¡Ý8 (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 ¡Ý8 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.
JIM-Study
Research protocol ¨C Version 1.9 ¨C May 24, 2013, Pagina 17
- 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.
- Explorative: To measure saliva IgG and IgA levels at T0 1 month (T1) and 1 year (T2) in all groups.
- Explorative: To measure B- and T-cell memory immune responses at T0, 1 month (T1) and 1 year (T2) in all groups.

Study description

Background summary

Neisseria meningitides is a gram-negative diplococcal bacterium that causes septicemia and meningitis. The incidence of meningococcal serogroup Y (MenY) appears to increase throughout countries in Europe, including the Netherlands. Nowadays, many young adults go travelling world-wide. Even though the increase of MenC in 1999/2000 was much more notable, the MenACWY-TT vaccine may be beneficial for a second vaccination at older age in the future. This second vaccination will protect the adolescents and maintain the herd immunity that persists up until today. Currently, a MenACWY-TT vaccination in adolescence is considered in many countries. However, longitudinal effectiveness studies with the MenACWY-TT vaccine for a second meningococcal vaccination are lacking. Therefore, the evaluation of persistence of antibodies, after a booster vaccination with MenACWY-TT is critical to monitor the duration of protection of a MenACWY-TT conjugate vaccine in adolescence after priming with MenC-TT at age of 14 months.

Study objective

The aim of this study is to investigate the immune response to the tetravalent MenACWY-TT vaccine administered as a second meningococcal vaccination and compare the booster response to MenC with the booster response to the monovalent MenC-TT conjugate vaccine.

Study design

T0 first visit:
- Sign informed consent form
- Draw first blood sample
- Draw first saliva sample
- Administer MenACWY-TT vaccination or second MenC-TT vaccination

T1 (1 month after T0)
- Draw second blood sample
- Draw second saliva sample

T2 (1 year after T0)
- Draw third blood sample
- Draw third saliva sample

Intervention

- Vaccination with Nimenrix or NeisVacC
- Venapunction
- Salivary

Contacts

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Eligibility criteria

Inclusion criteria

Participants are 10-, 12, and 15-year old children who have received a primary vaccination with a single dose of 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¡ãC) within 14 days before vaccination;
- Antibiotic use within 14 days of enrollment;
- Present evidence of serious disease(s) demanding medical treatment that might interfere the results of the study (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 any tetravalent MenACWY vaccination;
- Received any vaccination in the past month.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-03-2014
Enrollment:	410
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-02-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38656
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4286
NTR-old	NTR4430
CCMO	NL44863.100.13
OMON	NL-OMON38656

Study results