

Study to determine the appropriate age for a second immunization with the Meningococcal C conjugated vaccine.

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The main purpose of this study is to determine the appropriate age (10, 12 or 15 years) for a second MenC conjugate (MenCC) vaccine immunization in Dutch children that received a primary MenCC vaccination at a young age. A conclusion will be based...

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

Summary

ID

NL-OMON39602

Source

ToetsingOnline

Brief title

Second Immunization MenC study

Condition

- Bacterial infectious disorders

Synonym

vaccination against meningococcal C disease

Research involving

Human

Sponsors and support

Primary sponsor: RIVM

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

Intervention

Keyword: Meningococcus C, second, teenagers, vaccine

Outcome measures

Primary outcome

- To assess serum bactericidal antibody assay (SBA) levels at T0 and at 1 month (T1) and 1 year (T2) and 3 years (T3) after the second MenCC vaccination and determine whether there is a difference between the different age groups in the levels and the proportion of participants that have an SBA level of ≥ 8 (persistence of vaccine induced protective antibody levels).

Secondary outcome

- To assess serum MenC-PS specific IgG levels at T0 (prior to vaccination) and at 1 month (T1) and 1 year (T2) and 3 years (T3) after the second MenCC vaccination and determine whether there is a difference in IgG levels between the different age groups (persistence of vaccine induced antibody levels)

- To assess avidity of serum IgG antibodies and determine whether there is a difference in avidity between the different age groups

- To determine whether there is a difference in antibody subclasses (e.g. IgG1-4, IgG1/IgG2 ratio) between the different age groups.

- To assess whether there is a difference between the different age groups in the decay rate of MenC-PS specific antibody levels after secondary vaccination.

- To determine whether there is a difference in avidity of IgG antibodies after primary versus secondary vaccination.

- To investigate longitudinal kinetics of B- and T- cell memory immune responses after primary and secondary MenCC vaccination (e.g. presence and

functionality of memory B-cells and T-cells prior to and after the second MenCC vaccination).

- To measure serum IgG antibody levels against tetanus, the carrier protein for the MenC polysaccharide in the conjugate vaccine, to investigate the effect of a second MenCC vaccine on these titers.

- To measure salivary and serum IgA levels at T0, T1, T2 and T3 in order to investigate their correlation and the (longitudinal) kinetics of local and systemic IgA production after primary and secondary MenCC vaccination. IgA is the major antibody at mucosal surfaces and considered to be important in limiting meningococcal colonisation and preventing early invasion.

Study description

Background summary

In 2002 a Meningococcal serogroup C conjugated (MenCC) vaccination was implemented into the Dutch National Immunization Programme (NIP) for all children aged 14 months. In addition, a catch-up campaign was conducted between June and November 2002 during which all children between 1 and 18 years were invited to receive a single MenCC vaccination. Overall vaccine coverage was 94% and afterwards MenC disease disappeared in the vaccinated cohorts and even decreased dramatically in the non-immunized cohorts. It is suggested that the great success of the MenCC vaccination is primarily based on the catch-up campaign inducing large scale herd immunity by reducing the nasopharyngeal carriage of MenC bacteria in the population.

Available data derived from studies in the Netherlands and the UK now show that it might be necessary to introduce a second MenCC vaccine immunization in the NIP in order to maintain long-term individual and herd immunity against MenC. MenC-polysaccharide (MenC-PS) specific antibody levels decline rapidly after primary vaccination in young children. Protection induced by a primary MenCC vaccination appears to be age-dependant: cohorts vaccinated at older ages (up to adolescence/early adult) reveal greater and longer lasting protection than those routinely vaccinated in infancy. Next to an increased risk of invasive MenC disease in young children, there is an increased risk of invasive MenC disease during the teenage years. This suggests that a second

MenCC vaccination may be needed to maintain the successful contribution this vaccine has made to public (child) health in the Netherlands. Without a second dose of MenCC vaccine at an older age, children vaccinated at 14 months will reach the second period of increased risk for invasive MenC disease with low serologic markers of protective immunity.

Study objective

The main purpose of this study is to determine the appropriate age (10, 12 or 15 years) for a second MenC conjugate (MenCC) vaccine immunization in Dutch children that received a primary MenCC vaccination at a young age. A conclusion will be based on the quality and quantity of the MenC-PS specific antibody response against a second MenCC vaccination at these different ages .

Study design

Intervention study

T0: blood and saliva sampling followed by a one time vaccination with the registered MenC conjugated vaccin (NeisVac-C*)

T1 (28-42 days after T0): blood and saliva sampling

T2 (1 year after T0): blood and saliva sampling

T3 (3 years after T0): blood and saliva sampling

Intervention

One vaccination with the registered Meningococcal C conjugated vaccine (NeisVac-C*) at the beginning of the study.

Study burden and risks

Participants benefit from participating in the study by receiving an additional MenCC 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. NeisVac-C* is a registered vaccine 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 €35,- 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

Healthy children aged 10, 12 or 15 years
Vaccinated according to the Dutch National Immunization Programme (NIP)
Vaccinated (primed) with Meningococcal C conjugated vaccine one time at a young age

Exclusion criteria

- Severe acute (infectious) illness or fever ($>38.5^{\circ}\text{C}$) 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 MenCC 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
- Received vaccination within month prior to start of study

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2011
Enrollment:	268
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	NeisVac-C

Ethics review

Approved WMO

Date:	23-02-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	02-05-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	23-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	10-07-2014
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: 26279

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
EudraCT	EUCTR2011-000375-13-NL
CCMO	NL35207.100.11
OMON	NL-OMON26279