# Determine the appropriate age for a second immunization against MenC, an intervention study among Ducth adolescents.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON26279

**Source**
Nationaal Trial Register

**Brief title**
TIM-study

**Health condition**

To determine the appropriate age during adolescence (10, 12 or 15 years) for a second Meningococcal serogroup C conjugate vaccination, the quality and quantity of the MenC-PS specific antibody response after the MenCC vaccination are studied.

### Sponsors and support

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

### Intervention

## Outcome measures

### Primary outcome

To assess serum bactericidal antibody assay (SBA) levels at T0 and at 1 month (T1) and 1 year (T2) 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 ¡Ý8 (persistence of vaccine induced protective antibody levels).
To asses SBA levels 3 years after vaccination and to estimate long-term protection.

### Secondary outcome

1. To assess serum MenC-PS specific IgG levels at T0 (prior to vaccination) and at 1 month (T1) and 1 year (T2) 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);

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

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

4. 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;

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

6. 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);

7. 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;

8. To measure salivary and serum IgA levels at T0, T1 and T2 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.

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 objective

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.

### Study design

T0: Start of trial, first blood and saliva sampling followed by MenCC vaccination;

T1: 1 month after vaccination, blood and saliva sampling;

T2: 1 year after vaccination, blood and saliva sampling;

T3: 3 years after vaccination, blood and saliva sampling.

**Intervention**

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

Blood and saliva samplin prior to and 1 month and 1 year after vaccination.

# Contacts

**Public**
Antonie van Leeuwenhoeklaan 9, P.O.Box 1
W.A.M. Berbers
Bilthoven 3720 BA
The Netherlands
+31 (0)30 2742496
**Scientific**
Antonie van Leeuwenhoeklaan 9, P.O.Box 1
W.A.M. Berbers
Bilthoven 3720 BA
The Netherlands
+31 (0)30 2742496

# Eligibility criteria

## 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

1. Severe acute (infectious) illness or fever (>38.5 degrees C) within 14 days before vaccination;

2. Antibiotic use within 14 days of enrollment;

3. 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);

4. Known or suspected allergy to any of the vaccine components (by medical history);

5. Occurrence of (serious) adverse event after primary MenCC vaccination or other vaccination (by medical history);

6. Known or suspected immune deficiency;

7. History of any neurologic disorder, including epilepsy;

8. Previous administration of plasma products (including immunoglobulins) within the last 6 months;

9. Pregnancy;

10. Previous confirmed or suspected meningococcal disease;

11. Former received doses of MenC vaccines in addition to the primary vaccination;

12. Received vaccination within month prior to start of 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: | Recruitment stopped |
| Start date (anticipated): | 03-10-2011 |

| | |
|---|---|
| Enrollment: | 268 |
| Type: | Actual |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 10-07-2012 |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 39602
Bron: ToetsingOnline
Titel:

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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL3372 |
| NTR-old | NTR3521 |
| CCMO | NL35207.100.11 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON39602 |

## Study results

**Summary results**
N/A