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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26279

Bron
Nationaal Trial Register

Verkorte titel
TIM-study

Aandoening

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.

Ondersteuning

Primaire sponsor: National Institute for Public Health and Environment (RIVM, Bilthoven, The Netherlands)
Overige ondersteuning: National Institute for Public Health and Environment (RIVM, Bilthoven, The Netherlands)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	03-10-2011
Aantal proefpersonen:	268
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	10-07-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39602
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A