Juveniele Immunisatie Meningokokken ACWY studie

Gepubliceerd: 07-02-2014 Laatst bijgewerkt: 15-05-2024

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…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19891

Bron
NTR

Verkorte titel
JIM-studie

Aandoening

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

Ondersteuning

Primaire sponsor: National Institute for Public Health and Environment (RIVM)
Overige ondersteuning: GSK

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

- Vaccination with Nimenrix or NeisVacC
- Venapunction
- Salivary

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-03-2014
Aantal proefpersonen:	410
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-02-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38656
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten