Primary and booster meningococcal vaccination in Dutch elderly: study to investigate the immune response and determine functional antibodies after the tetravalent MenACWY-TT conjugate vaccine in the elderly population’

Gepubliceerd: 17-11-2020 Laatst bijgewerkt: 13-01-2025

booster superior compared to single vaccination

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

Samenvatting

ID

NL-OMON20287

Bron
Nationaal Trial Register

Verkorte titel
Men4age-study

Aandoening

meningococcal disease

Ondersteuning

Primaire sponsor: National Institute for Public Health and the Environment
Overige ondersteuning: Dutch Ministry of Health, Welfare and Sport

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective is to determine the level of protection in the elderly (divided into two age groups: 65-75 and 75-85 years of age) to the MenACWY-TT conjugate vaccine. The primary parameter to determine the level of protection will be by measuring meningococcal specific serum bactericidal antibody (SBA) levels pre-vaccination (T0) and 1 month (T1) and 1 year (T2) after vaccination. Also, in the booster-subcohort SBA levels will be determined 1 month (T3) and 1 year (T4) after the booster vaccination. At T4, blood samples will also be drawn and SBA levels determined from participants who did not receive a booster vaccination.

Toelichting onderzoek

Achtergrond van het onderzoek

Neisseria meningitides is a gram-negative diplococcal bacterium and is normally a commensal bacterium in the nasopharynx. However, it can be a devastating pathogen when it enters the blood stream causing invasive meningococcal disease. A substantial proportion of disease burden is in adults and the elderly show the highest case fatality rate by meningococci. Protecting the increasing elderly population against infectious diseases is essential to maintain healthy ageing. Vaccination of the elderly population might be beneficial for the individual by direct protection and, in addition, prevent spread of disease, leading to herd immunity. However, due to immunesenescence and waning efficacy of vaccines in elderly, it is challenging to maintain immunity after vaccination at a later age. Studies evaluating the efficacy and long-term persistence of antibodies after a primary immunization with MenACWY-TT conjugate vaccine in the elderly population are crucial but lacking. Also, no studies including a booster meningococcal vaccination have been conducted in this age group. The aim of this study is to investigate the immune response to a primary and a booster immunization with a tetravalent MenACWY-TT conjugate vaccine in elderly aged 65-85 years of age.

Doel van het onderzoek

booster superior compared to single vaccination

Onderzoeksopzet

T0, T1 (one month after vaccination), T2 (one year after vaccination, half of participants booster vaccination), T3 (one month after booster vaccination), T4 (two years after first vaccination)

Onderzoeksproduct en/of interventie

meningococcal conjugate vaccine

Contactpersonen

Publiek

RIVM
Milou Ohm

0302744246

Wetenschappelijk

RIVM
Milou Ohm

0302744246

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

■ Moderate to good general health with regard to age;
■ 65-85 years of age;
■ Provision of written informed consent;
■ Adherent to the protocol and available during the study period.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

■ Antibiotic use within 14 days of enrolment
■ Severe acute infectious illness or fever above 38.0 °C within 14 days before vaccination;
■ Present evidence of serious diseases either demanding regular use of oral immunosuppressive medical treatment, like corticosteroids, that might interfere with the results of the study within the last 3 months or demanding acute use of high dose oral immunosuppressive that might interfere with the results of the study within the last 2 weeks;

■ Known or suspected allergy to any of the vaccine components (by medical history);
■ Occurrence of a serious adverse event after other vaccination by medical history;
■ Known or suspected immune deficiency;
■ Known or suspected coagulation disorder;
■ Oral hormone use, such as postmenopausal hormones, within the last 3 months;
■ History of one of the following neurological disorders: multiple sclerosis, Parkinson’s disease, or epilepsy;
■ Previous administration of plasma-serum products including immunoglobulins within 6 months before vaccination and blood sampling;
■ Serious surgery within the last 3 months;
■ Previous vaccination with the MenC, MenC-TT or MenACWY-TT vaccine;
■ Previous confirmed or suspected meningococcal disease;
■ Any vaccination within a month before enrolment.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	140
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54103
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9054
CCMO	NL72728.100.20
OMON	NL-OMON54103

Resultaten