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’

Published: 17-11-2020
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booster superior compared to single vaccination

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20287

Source
Nationaal Trial Register

Brief title
Men4age-study

Health condition

meningococcal disease

Sponsors and support

Primary sponsor: National Institute for Public Health and the Environment
Source(s) of monetary or material Support: Dutch Ministry of Health, Welfare and Sport

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

■ To compare SBA levels of ≥8 (persistence of vaccine induced protective antibody levels) at 1 month and 1 year after the booster vaccination between the single vaccination cohort and the booster vaccination cohort ■ To determine serum MenA-PS, MenC-PS, MenW-PS and MenY-PS specific IgG levels at 1 month and 1 year and compare between the single vaccination cohort and booster cohort at 1 month and 1 year after the booster vaccination ■ To determine serum IgG antibody levels against tetanus, the carrier protein for both vaccines, at 1 month and 1 year and compare between the single vaccination cohort and booster cohort at and 1 month and 1 year after the booster ■ To determine serum IgA and IgM levels against MenA, MenC, MenW and MenY at 1 month and 1 year and compare between the single vaccination cohort and booster cohort at 1 month and 1 year after the booster vaccination ■ To determine MenC-PS specific IgG subclasses (IgG1/IgG2 ratio) and avidity at 1 month and 1 year and compare the single vaccination cohort and booster cohort at 1 month and 1 year after the booster vaccination ■ Explorative: to explore possible differences in protective levels against at all timepoints between sub age groups (65-75 years and 75-85 years of age)

Study description

Background summary

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.

Study objective

booster superior compared to single vaccination

Study design

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)

Intervention

meningococcal conjugate vaccine

Contacts

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Eligibility criteria

Inclusion criteria

■ 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.

Exclusion criteria

■ 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	140

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 17-11-2020

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54103
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results