Strengthening memory immunity in the aged population by vaccinating pre-elderly

No registrations found.

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

Summary

ID

NL-OMON25211

Source
NTR

Brief title
StimulAge-study

Health condition

vaccin, pre-elderly, immunesenescence, ageing, biomarkers

Sponsors and support

Primary sponsor: RIVM, UMCG
Source(s) of monetary or material Support: RIVM

Intervention

Outcome measures

Primary outcome

Determine differences in vaccine response in the pre-elderly age group (50-65) to the MenACWY-TT and VZV vaccine. Primary parameters to determine these differences will be:

-MenACWY-TT: Meningococcal specific serum bactericidal antibody (SBA) levels pre-vaccination (T0) and 7 days (T1), 28 days (T2), and 1 year (T3) post-vaccination.

-VZV: memory T cell responses against VZV pre-vaccination (T0) and 14 days (T1), 28 days (T2), and 1 years (T3) post-vaccination.

Secondary outcome

-Determine biomarkers associated with the immunesenescence process and correlate these to the vaccine response.

-To determine Meningococcal specific IgG, IgM, IgA, IgG-subclasses and avidity;

-To determine VZV specific IgG responses in serum

-To determine general health status of the participant using a short questionnaire

-Explorative: To determine Meningococcal specific B cell responses

-Explorative: To determine Tetanus specific B and T cell responses

Study description

Background summary

The world population is ageing. In 2060 about 30% of the population is predicted to be above 65 years, compared to 17.4% in 2010. Ageing of the world population forms one of the major challenges of the 21st century. Population ageing has implications for the medical conditions, as with age the vulnerability for chronic diseases and severe infections increases. Prevention of infectious diseases by timely immunization of the elderly population is a prerequisite to establish healthy ageing.Due to the demographic changes in the future population, vaccination programmes need to shift to a life-course scheme. Childhood vaccinations remain extremely important to induce immunity, but it is also necessary to maintain immunity afterwards, before reaching old age. Immunization of elderly is challenging, due to changes in the immune system with age, which cause difficulties to respond to vaccination (immunesenescence). It has been suggested that immunization against antigens has to be established before the onset of immunesenescence, most probably in the 5th or 6th decade of life. Using this strategy, the protection of elderly against infectious diseases might be improved. Biomarkers that predict
vaccination responses earlier in life might also help to protect the aged population, since precautions can be taken before the onset of immunesenescence when low response to the vaccination is expected.

The main objective of this study is to determine remarkable differences in vaccine responses

in the pre-elderly age group (50-65 years of age) to a primary immunization with vaccine antigens to which no or (very) low pre-vaccination antibody levels and memory cells exist.

The MenACWY-TT (against Meningococcal ACWY) and VZV (against Varicella Zoster) vaccines will be used to study these differences.
Moreover, the utility of biomarkers that predict the responsiveness of pre-elderly persons will be explored.

Study objective

The main objective of this study is to determine remarkable differences in vaccine responsesin the pre-elderly age group (50-65 years of age) to a primary immunization with vaccine antigens to which no or (very) low pre-vaccination antibody levels and memory cells exist.

The MenACWY-TT (against Meningococcal ACWY) and VZV (against Varicella Zoster) vaccines will be used to study these differences. Moreover, the utility of biomarkers that predict the responsiveness of pre-elderly persons will be explored.

Study design

MenACWY: before vaccination (T0), post-vaccination: 7 days (T1), 28 days (T2), and 1 year (T3)

VZV: before vaccination (T0), post-vaccination: 14 days (T1), 28 days (T2), and 1 year (T3)

Intervention

Two different study populations will be recruited, one group will be administered the MenACWY-TT vaccine and the other group the VZV vaccine. For the MenACWY-TT study group 200 persons will be included. Blood samples will be drawn pre-vaccination (T=0). Post-vaccination blood
samples will be drawn at 7 days (T=1), 28 days (T=2) and 1 year (T=3).

In the VZV study group 50 persons will be included, since it is considered a pilot study. Blood samples will be drawn pre-vaccination (T=0).
Postvaccination
blood samples will be drawn after 14 days (T=1), 28 days (T=2), and 1 year (T=3). Moreover, participants of both study groups will be asked whether we are allowed to contact them again, for example for an extra blood sampling after 5 years. At T=0 and T=3 participants will be asked to fill in a general health questionnaire.

Contacts

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Eligibility criteria

Inclusion criteria

-Good general health;

-50-65 years of age;

-Provision of written informed consent;

-Adherent to protocol and available during the study period.

Exclusion criteria

-Antibiotic use or fever (>38 °C) within 14 days of enrollment;

-Present evidence of serious disease(s) demanding immunosuppressive medical treatment, like corticosteroids, that might interfere with the results of the study within the last 3 months;

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

-Occurrence of serious adverse event after other vaccination (by medical history);

-Known or suspected immune deficiency;

-Known or suspected coagulation disorder;

-Hormone use, such as post-menopausal hormone or contraceptive pills, within the last 3 months;

-History of any neurologic disorder, including epilepsy;

-Previous administration of 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. (for the MenACWY-TT study group)

-Previous meningococcal episode (MenACWY-TT study group)

-Previous vaccination with VZV vaccine (for the VZV study group)

-Previous Varicella Zoster episode (VZV study group)

-Vaccination with DT, DT-IPV, TdaP or T within the past 5 years (for the MenACWY-TT study group);

-Any vaccination within a month before enrollment;

-Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	15-09-2014
Enrollment:	250
Type:	Anticipated

Ethics review

Positive opinion
Date: 27-06-2014
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47511
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4518
NTR-old	NTR4636
CCMO	NL48510.100.14
OMON	NL-OMON47511

Study results

Summary results
N/A