Vaccination, Immunity and Aging Research

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We hypothesize that frailty in older individuals might underly low responses to the 23-valent polysaccharide pneumococcal vaccination (PPV23) that will be implemented in the National immunization program in autumn this year for elderly 73-79 years...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23996

Bron
Nationaal Trial Register

Verkorte titel
VIVO

Aandoening

not applicable

Ondersteuning

Primaire sponsor: RIVM
Overige ondersteuning: RIVM

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Assess the relation of frailty in 73-79 years old male and female persons with antibody responses to both vaccine pneumococcal polysaccharide serotypes and the Influenza virus

vaccine strains by measuring HI titers pre and 4-6 weeks post vaccination.

Toelichting onderzoek

Achtergrond van het onderzoek

With ageing there is a decline in the functioning of the immune system, making older people more vulnerable for infections and resulting in a smaller boost of the immune system in response to vaccination. Since there is great heterogeneity in the rate at which immune function declines, it is important to identify elderly at risk for low vaccination responses and thus at higher risk for infection. We hypothesize that frailty in older individuals might underly low responses to the 23-valent polysaccharide pneumococcal vaccination (PPV23) that will be implemented in the National immunization program in autumn this year for elderly 73-79 years of age.
To study this hypothesis, we will capitalize on the infrastructure and data provided by the ongoing longitudinal Doetinchem Cohort Study (DCS) (NL63779.041.17), which includes available frailty data of all participants, to assess the immune response to PPV23 and the yearly Influenza vaccine in relation to frailty. In the DCS, persons originally 20-59 years of age at study start, have been followed for over 30 years (N>3700). Various frailty parameters have been assessed in these participants. Based on these, a frailty score (index) has been determined by using the most recent information on 36 frailty-related “health deficits”, i.e. specific (co)morbidities, tests of physical (dys)functioning and cognition . Because of these data the DCS provides a unique opportunity to get insight into factors contributing to vaccine immunogenicity in older persons. Recent data from a sub-cohort of the DCS aged 60-80 years revealed that lingering inflammation is associated with frailty. Therefore frailty may be linked to reduced immune function and vaccination responses.

Doel van het onderzoek

We hypothesize that frailty in older individuals might underly low responses to the 23-valent polysaccharide pneumococcal vaccination (PPV23) that will be implemented in the National immunization program in autumn this year for elderly 73-79 years of age.

Onderzoeksopzet

Visit T0 (-4 till 0 week pre vaccination); Visit T1 (4-6 weeks post vaccination); Visit T2 (10-11 months post vaccination); Visit T3 (22-24 months post vaccination)

Onderzoeksproduct en/of interventie

venapunction

Contactpersonen

Publiek

RIVM
Linde Woudstra

0031 030 2744079

Wetenschappelijk

RIVM
Linde Woudstra

0031 030 2744079

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Participant in round 6 of the Doetinchem Cohort study and born between 1941-1947
• Willing to receive the PPV23 vaccine in 2020
• Have signed Informed Consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Having had a previous pneumococcal vaccination
• Known or suspected allergy to any of the vaccine components or having experienced a previous severe adverse reaction to any vaccine.
• Receipt of any high-dose (≥ 20 mg of prednisone daily or equivalent) daily corticosteroids (locally applied including inhaled steroids are acceptable) within 2 weeks of study entry.
• Repeated use of any high dose of corticosteroids (a dose of > 30 mg of prednisone or equivalent per day for multiple days) in the last month.
• Receipt of a recent organ- or bone marrow transplant during the last 5 years .
• Have an anatomical or functional asplenia.
• Receipt of blood products or immunoglobulin, within one month of the study entry.
• Known or suspected coagulation disorder that in the opinion of the investigator would contraindicate against receiving an intramuscular injection or undergo frequent blood

sampling.
• Known to be positive for human immunodeficiency virus (HIV), and/or hepatitis C virus (HCV) and/or hepatitis B virus (HBV).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
Not applicable

Ethische beoordeling

Positief advies

Datum:	03-08-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8812
Ander register	METC Utrecht : METC 20-510

Resultaten