Pneumococcal vaccine against atherosclerosis

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We hypothesize that prevenar 13 elicits a humoral immune response against oxidized low density lipoprotein

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21732

Bron
NTR

Verkorte titel
N.A.

Aandoening

Atherosclerosis

Ondersteuning

Primaire sponsor: N.A.
Overige ondersteuning: Via Consortium, sponsored by EU

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Efficacy endpoints
- Total IgG, IgM, immunoglobin E (IgE), immunoglobin A (IgA) titers
- Anti-oxLDL IgG, IgM, IgE, IgA titers

- Anti-pneumococcal wall polysaccharide IgG, IgM, IgE, IgA titers
- OxLDL levels
- Immunoglobin (Ig)-oxLDL complexes
- Total serum cholesterol, LDL, HDL, triglycerides and lipoprotein(a) (Lp(a))

Tolerability / safety endpoints
- Treatment-emergent (serious) adverse events (S)AEs
- Concomitant medication
- Clinical laboratory tests (haematology, chemistry (including cortisol and aldosterone) and urinalysis)
- Vital signs (pulse rate, systolic blood pressure and diastolic blood pressure)
- Electrocardiogram (ECG) (heart rate (HR), PR, QRS, QT, QTc)

Toelichting onderzoek

Achtergrond van het onderzoek

In this study, 24 healthy subjects will undergo placebo-controlled injections with Prevenar 13. The humoral response against oxLDL will be measured, as well as the effect on blood cholesterol levels.

Recruitment will take place in the Netherlands

Doel van het onderzoek

We hypothesize that prevenar 13 elicits a humoral immune response against oxidized low density lipoprotein

Onderzoeksopzet

Week 0, 1, 2, 3, 4, 8, 12, 16, 20, 24, 28, 32, 44, 56 and 68

Onderzoeksproduct en/of interventie

Prevenar13

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Male, aged 18-45 without evidence of any active or chronic disease following a medical history, a complete physical examination including vital signs, 12-lead ECG, haematology, blood chemistry and urinalysis.

2. Able to participate and willing to give written informed consent and to comply with the study restrictions

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. Subjects vaccinated with a pneumococcus vaccine

2. Known allergy against any of the excipients of the Prevenar vaccine.

3. History or symptoms of any significant disease including (but not limited to), neurological, psychiatric, endocrine, cardiovascular, respiratory, gastrointestinal, hepatic, or renal disorder.

4. History of splenectomy.

5. History of active malignancy within the last 5 years, with the exception of localized or in situ carcinoma (e.g., skin basal or squamous cell carcinoma).

6. Positive Hepatitis B surface antigen (HBsAg), Hepatitis C antibody (HCV Ab), or human immunodeficiency virus antibody (HIV Ab) at screening.

7. Clinically significant abnormalities, as judged by the investigator, in laboratory test results (including hepatic and renal panels, complete blood count, chemistry panel and urinalysis). In the case of uncertain or questionable results, tests performed during screening may be repeated before randomization to confirm eligibility or judged to be clinically irrelevant for healthy subjects.

8. Participation in an investigational drug study within 3 months prior to screening.

9. Loss or donation of blood over 500 mL within three months (males)prior to screening.

10. Concomitant disease or condition that could interfere with, or for which the treatment of might interfere with, the conduct of the study, or that would, in the opinion of the Investigator, pose an unacceptable risk to the subject in this study.

11. Any confirmed significant allergic reactions (urticaria or anaphylaxis) against any drug, or multiple drug allergies (non-active hay fever is acceptable).

12. Unwillingness or inability to comply with the study protocol for any other reason.

13. Active infection at the time of baseline visit, as evidence by either a body temperature >37.5 °C.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	04-04-2016
Aantal proefpersonen:	24
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL5826
NTR-old	NTR5981
Ander register	: CHDR1503

Resultaten

Samenvatting resultaten
N.A.