Pneumococcal vaccine against atherosclerosis

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21732

Source
NTR

Brief title
N.A.

Health condition

Atherosclerosis

Sponsors and support

Primary sponsor: N.A.
Source(s) of monetary or material Support: Via Consortium, sponsored by EU

Intervention

Outcome measures

Primary outcome

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)

Secondary outcome

N.A.

Study description

Background summary

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

Study objective

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

Study design

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

Intervention

Prevenar13

Contacts

Public

Zernikedreef 8

Centre for Human Drug Research
Leiden 2333 CL
The Netherlands
+ 31 71 5246 400

Scientific

Zernikedreef 8

Centre for Human Drug Research
Leiden 2333 CL
The Netherlands
+ 31 71 5246 400

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2016
Enrollment:	24
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5826
NTR-old	NTR5981
Other	: CHDR1503

Study results

Summary results
N.A.