Generating normal values for antibody response in "healthy" patients of age

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To generate a set of normal values in people over 60 that can be expected to have an normal immune system, in order to be able to interpret the immune system of eldery patients with repeated airway infections.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immunodeficiency syndromes
Study type	Interventional

Summary

ID

NL-OMON44308

Source
ToetsingOnline

Brief title
IRGO: Immuun Response in "Healthy" patients of age

Condition

- Immunodeficiency syndromes

Synonym
Immune deficiency

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anti body response, Healthy patients of age, Normal values, Vaccination

Outcome measures

Primary outcome

Generate a set of normal values for vaccin responses and T- and B-cel

subpopulations in peripheral blood in elderly people which can be expected to

have a normal immune system.

Secondary outcome

NA.

Study description

Background summary

For the interpretation of vaccin responses and the numbers of relevant subpopulations of T-and B -cells in peripheral blood.of elderly patients with repeated airway infections that are screened for an immune deficiency, we are in need for normal values for this specific population. Currently we use normal values that were obtained in young adults and we have reasons to believe that the normal values of young adults aredifferent from the those in elderly > 60 years. To obtain normal values for this latter population we want to approach patients that visit the outpatient clinic for chronci coughing, but have no signs of an underlying immune deficiency, nor any other underlying disease that may have an impact on the immune parameters under study.

Study objective

To generate a set of normal values in people over 60 that can be expected to have an normal immune system, in order to be able to interpret the immune system of eldery patients with repeated airway infections.

Study design

Observational study with intervention.

Intervention

Two vaccinations (tetanus and 23-serotypes containing pneumococcal polysaccharide vaccin) and venapuncture.

Study burden and risks

There are no risks associated with study participations. Participants may experience some discomfort at the site of application of the vaccins for a maximum of 2 days. Futhermore an extra venapuncture may be necessary in case a blood draw cannot be combined with one for regular blood tests.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Cough e.c.i.

Exclusion criteria

use of immuunsupressives
infectious diseases such as RA, IBD or asthma in medical history or suspicion having one HIV infection

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	15-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL62634.018.17