

# 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 elderly patients with repeated airway infections.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Immunodeficiency syndromes
<b>Study type</b>	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 are different 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

### Public

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### Scientific

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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 immuunsuppressives  
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