# De role of Cytomegalovirus-infection on T-cell dynamics after influenza vaccination in elderly

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To investigate the effect of cytomegalovirus(CMV)-infection on the production rate and death rate of T cells after influenza vaccination in elderly.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON43423

**Source**
ToetsingOnline

**Brief title**
DICE (Dynamics of t-cells In Cytomegalovirus-infected Elderly)

### Condition

- Other condition

**Synonym**
CMV ageing

**Health condition**

immuunsysteem

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** RIVM
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** T-cell Dynamics Cytomegalovirus Ageing

## Outcome measures

### Primary outcome

The average production rate and lifetime of different T-cell populations after influenza vaccination in CMV-positive and CMV-negative elderly (phase 2).

### Secondary outcome

- Absolute numbers of different T-cell populations during the study period (both on base of phenotype markers as CMV-specific and influenza-specific T cells) (phase 2)

- The presence/amount of CMV virus shedding in healthy individuals in saliva (phase 1)

- The presence and level of CMV IgG antibodies (phase 1 and 2)

- The presence/amount of CMV DNA and RNA in monocytes in CMV-positive individuals (phase 1)

- Functionality of T cells against CMV (phase 1 and 2)

# Study description

### Background summary

Infection with Cytomegalovirus (CMV) in healthy individuals does not cause clinical symptoms. However, it is associated with enhanced immunosenescence (aging of the immune system) and therefore can lead to decreased efficiency of

(influenza) vaccines. The mechanism behind this impaired immune response to new antigens in CMV-infected elderly is unknown. CMV has a great influence on the composition of the T cell compartment in elderly. It induces great numbers of memory cells, which might have a competing function with memory cells to other antigens, such as for influenza. In this study, we want to test the hypothesis that the production rate and/or death rate of T cells after an influenza vaccination is lower in CMV-positive compared to CMV-negative elderly.

## Study objective

To investigate the effect of cytomegalovirus(CMV)-infection on the production rate and death rate of T cells after influenza vaccination in elderly.

## Study design

The study is longitudinal and consist of two phases; (1) CMV reactivation and screening study and (2) the heavy water study. Phase (1) consists of one blood- and saliva collection on the day of inclusion. First we include 40 participants. In the case that we cannot select the 10 participant for phase 2 of the study from these 40 participants, we will include another 20 participants (thus 60 in total). Phase (2) consists of (A) temporarily drinking of heavy water, (B) an seasonal influenza vaccination and (C) frequent collection of blood and urine samples. In total, the study will take around 2 years.

## Intervention

Intervention: In phase 2 of the study, the ten participants will receive the seasonal influenza vaccination of 2016/2017.

Invasive procedures: One blood sample and one saliva sample will be collected from the participants in phase 1. In phase 2, blood (8 times, in total 816 ml in 1 year in phase 2) and urine (13 times, of which 6 by mail) will be collected frequently. A short questionnaire (about the health status since last blood collection) will also be performed by the researcher during each visit of the participant to the hospital.

Imposed behaviour: Only applicable for participants of phase 2 to measure T cell dynamics; drinking the start bolus of heavy water of circa 350 ml on day 0, followed by a daily dose of about 60 ml heavy water for 5 weeks.

## Study burden and risks

Participants of phase 1 of the study will visit the UMC Utrecht 1 time during which blood and saliva will be collected. The selected 10 participants of phase 2 will visit the UMC Utrecht another 10 times of which 1 visit (visit 3)

will take a whole day. In one visit (visit 1) the influenza vaccination will be given Participants will drink heavy water for 5 weeks, which can cause on the first day (because of the greater amount of heavy water) some nausea and/or dizziness. During the other 5 weeks, the participants will drink daily a smaller amount of heavy water.

In the 10 visits blood will be collected (30,5 to 111,5 ml per time) of in total 874 ml in approximately 1 year, which is within the policy of Sanquin blood bank. During 7 visits, and 7 times by mail, a urine sample will also be handed in (13 times in total).. In the case that a participant is suffering from influenza-like-illness, a nose and throat swab will be taken during a home visit to identify influenza-infection

The risks of venepuncture, the registered influenza vaccine and drinking of heavy water is minimal. Although the physical burden of the study is minimal, there is some personal burden for participants; the time and energy that participants should invest for the hospital visits and blood collections and the traveling to and from the hospital.

# Contacts

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RIVM

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

healthy elderly between 60 and 80 years old

## Exclusion criteria

- Immune related diseases (allergies, diabetes etc)
- Medicine use (heart, kidney failure etc)
- (A history of) cancer
- Drugs or extensive alcohol use
- Allergy for influenza vaccine
- Sea- or motion sickness

# Study design

## Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 09-06-2016 |
| Enrollment: | 60 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 17-02-2016 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 11-05-2016 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 21-10-2016 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 | NL56041.041.15 |

# Study results

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| Date completed: | 08-01-2019 |
| Actual enrolment: | 60 |