# An exploratory study to assess the RSV titer in healthy volunteers as guidance for the main study

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To determine pre-existing virus neutralization titer levels against RSV in a general healthy population (immunogenicity is a secondary study objective (proof-of concept) in the main phase I study).

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Respiratory tract infections |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON44515

**Source**
ToetsingOnline

**Brief title**
RSV titer assessment in healthy adult volunteers

### Condition

- Respiratory tract infections

**Synonym**
common cold, RSV infection

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Intravacc
**Source(s) of monetary or material Support:** Intravacc

## Intervention

**Keyword:** antibody, reference, RSV, titer

## Outcome measures

### Primary outcome

Virus neutralization titer levels against RSV

### Secondary outcome

NA

# Study description

### Background summary

Intravacc is developing a live-attenuated recombinant respiratory syncytial virus (RSV) vaccine. With reverse genetics, a virus was constructed from which the coding sequence for the G attachment protein was deleted from the RSV genome. The resulting RSV*G lacks the G protein resulting in severely impaired binding to host cells and reduced infectivity. Due to this attenuation and limited spread, the vaccine is expected to induce an effective immune response, without inducing RSV symptoms. The phase I study (main study) will evaluate the safety, tolerability and shedding of the RSV vaccine in healthy adults. An objective will be to evaluate the immunogenicity of the vaccine, the capacity of the RSV*G vaccine to induce a humoral immune response both systemically and mucosally (proof-of-concept). Because RSV is a common cold virus, all subjects will have experienced multiple infections with RSV and have pre-existing immunity. Therefore, true proof-of-concept, i.e. induction of a functional and protective primary immune response, can only be established in naïve individuals (infants). However, a. for prophylactic vaccines safety in healthy adults is required before proceeding to target populations such as children and infants and b. it is also of interest to study whether the vaccine is capable of activating the immune system. The vaccine may boost pre-existing immunity and induce new immune responses to sub-immunodominant epitopes in the F and SH surface proteins.
A four-fold increase in RSV serum virus neutralizing antibody titers 28 days after immunization is indicative for the activation of an immune response against RSV. For the main study, one of the inclusion criteria is a pre-existing virus neutralization titer against RSV below a certain level (to be determined based on the results of the pilot study) at screening. RSV neutralizing antibody titers can neutralize the vaccine upon administration and

thereby prevent infection, and thereby decrease the effectiveness of the vaccine. Secondly, when high pre-vaccination titers are present, a rise in antibody titers induced by the vaccine may not be measurable.

### Study objective

To determine pre-existing virus neutralization titer levels against RSV in a general healthy population (immunogenicity is a secondary study objective (proof-of concept) in the main phase I study).

### Study design

Virus neutralization titer levels against RSV will be determined in 4.0 mL serum blood samples (RSV-specific IgG). These samples will be collected from a planned total number of 100 healthy male/female subjects (a single blood sample donation).

### Study burden and risks

1 short visit with 1 blood sample, low risk low burden.

## Contacts

**Public**
Intravacc

Antonie van Leeuwenhoeklaan 9
Bilthoven 3721 MA
NL
**Scientific**
Intravacc

Antonie van Leeuwenhoeklaan 9
Bilthoven 3721 MA
NL

## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

1.Healthy male or female subjects, 18-45 years of age, inclusive;
2.Signed informed consent prior to any study-mandated procedure
3. Has the ability to communicate well with the Investigator in the Dutch language

## Exclusion criteria

1. Immune-compromised individuals (known or expected immune deficiency, disease or use of medication that may affect the immune system);
2. Chronic airway diseases;
3. Airway infection / common cold within 14 days prior to blood sample collection;
4. Hay fever or other allergies that involve the airways;
5. Blood donation would result in loss of blood outside the limits of the national blood bank (>500 mL within 90 days.

# Study design

## Design

**Study type:** Observational invasive

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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): | 15-06-2017 |
| Enrollment: | 100 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 09-06-2017 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

# 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 | NL62098.056.17 |