# An open phase 1, dose-escalating, clinical trial on the safety of a new liposomal adjuvant system, CAF01, when given with the tuberculosis subunit vaccine Ag85B-ESAT-6 as two injections with two months interval to healthy adult volunteers.

Published: 08-06-2009
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Primary:The primary objective is to evaluate the safety profile of an adjuvated Tb subunit vaccine (CAF01) administered in 50 µg Ag85B-Esat-6 alone, 50 µg Ag85B-Esat-6 alone with three escalating CAF01 dose levels, to four groups of healthy…

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| **Ethical review** | - |
| **Status** | Recruitment stopped |
| **Health condition type** | Mycobacterial infectious disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON33959

**Source**
ToetsingOnline

**Brief title**
ACAF01-01

### Condition

- Mycobacterial infectious disorders

**Synonym**
Prevention, Tuberculosis

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Statens Serum Institut
**Source(s) of monetary or material Support:** SSI (Statens Serum Institut)

## Intervention

**Keyword:** ADJUVATED, HEALTHY VOLUNTEERS, TUBERCULOSIS, VACCINE

## Outcome measures

### Primary outcome

Safety variables:

- Adverse reactions with onset between the first vaccination and 24 weeks after the second vaccination either identified during medical examinations, as diary records, or during safety interviews

- Changes form baseline in safety laboratory test values 1 day, 7 days and 6 weeks after the first and second vaccinations and 24 weeks after the second vaccination.

### Secondary outcome

Immunogenicity variables

- Changes from baseline in Ag85B-Esat-6 induced IFN-gamma release from PBMC's measured by ELISA, 1 week and 6 weeks after the first and second vaccinations and 24 and 44 weeks after the second vaccination.

- Changes from baseline in Ag85B-ESAT6 IFN-gamma spot forming cells measured by ELISPOT, 1 week and 6 weeks after the first and second vaccinations and 24 and 44 weeks after the second vaccination.

- Changes from baseline in serum Ig-G antibodies against Ag85B-ESAT-6, 6 weeks after the first and second vaccinations and 24 and 44 weeks after the second vaccination.

# Study description

**Background summary**

Title:
A safety and immunogenicity phase 1 trial with an adjuvated TB subunit vaccine (Ag85B - Esat-6 + CAF01) administered in PPD positive volunteers at 0 and 2 months.

Background:
Tuberculosis (TB) is caused by Mycobacterium tuberculosis (MT), an intracellular pathogen. One third of the worlds population is infected with TB, 8-10 milion suffer from TB-disease and 2-3 million die annualy. Currently the only available vaccine against TB is BCG. BCG protects against severe childhood forms of TB. However, the protective efficacy in adult pulmonary tuberculosis varies considerably, from 85% to 0%. A new improved second generation TB vaccine is therefore urgently needed.

**Study objective**

Primary:

The primary objective is to evaluate the safety profile of an adjuvated Tb subunit vaccine (CAF01) administered in 50 µg Ag85B-Esat-6 alone, 50 µg Ag85B-Esat-6 alone with three escalating CAF01 dose levels, to four groups of healthy volunteers at 0 and 2 months, injecting two doses.

Secondary:

The secondary objective is to determine the immunogenicity profile of an

adjuvant TB subunit vaccine (CAF01) administered in 50 µg Ag85B-Esat-6 alone, 50 µg Ag85B-Esat-6 alone with three escalating CAF01 dose levels, to four groups of healthy volunteers at 0 and 2 months, injecting two doses.

### Study design

A single-centre, open, phase 1 trial with a fixed antigen but a variable doses of adjuvant, including four groups of volunteers. In total 37 volunteers, vaccinated twice, 0 and two months. A data Safety Monitoring Board (DSMB) decided if it is safe to continue with the second vaccination.

### Intervention

Two vaccinations over a two month period, intramuscularly into deltoid muscle.

### Study burden and risks

Twice a vaccination. Ten times blood withdrawal, Mantoux-skin-test.

Risks: anafylactic shock caused by the vaccine.

## 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

Female and male (18-55 years)
Healthy

## Exclusion criteria

History of tuberculosis or known exposure
Positive Tuberculin Skin Test and/or positive Quantiferon
BCG vaccination
Thyroid dysfunction
Disease affecting the lymphoid organs
ANA-titer, HBV, HCV, HIV
C-reactive protein level >50 mg/l
Live vaccine vaccination within 3 months before the first vaccination
Intake of another clinical trial product/vaccine within 3 months from the first vaccination or participation in previous clinical trials with the Ag85B-Esat-6 antigen.

# Study design

## Design

**Study type:** Interventional

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 16-11-2009 |

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| Enrollment: | 37 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 06-11-2012 |
| Application type: | Amendment |
| Review commission: | CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag) |

## 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 |
|---|---|
| EudraCT | EUCTR2008-006003-23-NL |
| CCMO | NL26270.000.09 |