# Specific B-cell Memory After a Single Dose or Booster MenC Conjugate Vaccination: a Pilot Study in Adults

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How long does B-cell memory persist after a single conjugate MenC vaccination and which cells are involved? How is this related to the age of first vaccination? And how to define correlates of protection for immunity and memory after MenC conjugate...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Bacterial infectious disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON30102

**Source**
ToetsingOnline

**Brief title**
B-cell Memory After MenC Vaccination

### Condition

- Bacterial infectious disorders

**Synonym**
bacterial meningitis, spotted fever

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** - Memory B-cells, - MenC, - Vaccination

## Outcome measures

### Primary outcome

Characterization of the memory B-cell response after MenC (conjugate)

vaccination, using Luminex bead based array technology, serum bactericidal

antibody assay (SBA), FACS analysis and ELISPOT assay.

### Secondary outcome

niet van toepassing

# Study description

### Background summary

Bacterial meningitis is caused by several well-known polysaccharide-coated pathogens such as Haemophilus influenza type B (Hib) Streptococcus pneumoniae and Neisseria meningitidis serogroup C (MenC). A single MenC polysaccharide-protein conjugate vaccination was introduced into the National Vaccination Program (RVP) at the age of 14 months in 2002. Furthermore in 2002, in a large national campaign all children and adolescents between the age of 1 and 18 years received one dose of MenC conjugate vaccine.
In the following years it will become clear how effective MenC vaccination is in the long term. Long term protection is mainly based on memory after vaccination or natural infection. In the Netherlands MenC memory is induced by a single vaccination. The cellular and molecular pathways for induction of MenC memory (or any other protein conjugated polysaccharide for that matter) are not totally clear.

### Study objective

How long does B-cell memory persist after a single conjugate MenC vaccination and which cells are involved? How is this related to the age of first vaccination? And how to define correlates of protection for immunity and memory after MenC conjugate vaccination?

### Study design

Pilot in healthy adults. After MenC conjugate vaccination, IgG antibody levels, kinetics, avidity, bactericidal activity and circulating MenC polysaccharide specific B-cells will be evaluated.

### Intervention

One group receives a primary MenC conjugate vaccination; the other two groups receive either a conjugate MenC or polysaccharide MenC booster vaccination. Blood will be drawn before and several time points after vaccination.

### Study burden and risks

Study participants will be (re)vaccinated with licensed MenC conjugate or polysaccharide vaccine and will be asked to donate a blood sample pre-vaccination and at several pre-set time points after vaccination, a total of 9 blood samples are drawn, each of 20-30 ml, up to maximal 250 ml divided over 9 time points in 4 weeks .

## Contacts

**Public**
RIVM

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**Scientific**
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

- Good general health;
- Provision of written informed consent;
- Adherent to protocol, and available during the study period.

## Exclusion criteria

- Severe acute (infectious) illness of fever (>38.5°C) within 2 weeks before vaccination;
- Present evidence of serious disease(s) demanding medical treatment that might interfere the results of the study;
- Known or suspected allergy to any of the vaccine components (by medical history);
- Known or suspected immune deficiency;
- History of any neurologic disorder, including epilepsy;
- Previous administration of plasma products (including immunoglobulins) within the last year;
- Pregnancy.

# Study design

## Design

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|---|---|
| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Prevention |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 04-05-2007 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 11-09-2006 |
| Application type: | First submission |
| 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 | EUCTR2006-002358-31-NL |
| CCMO | NL12447.000.06 |