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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27223

Source
NTR

Brief title
B-cell Memory After MenC Vaccination

Health condition

MenC conjugate vaccination, Memory B cells, infectious diseases, meningitis

Sponsors and support

Primary sponsor: National Institute for Public Health and the Environment (RIVM)
Laboratory for Vaccine Preventable Diseases (LTR)
Antonie van Leeuwenhoeklaan 9
3721 MA Bilthoven
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

- How long does B-cell memory persist after a single conjugate MenC vaccination in adults and which cells are involved?

Secondary outcome

- How long do serum SBA titers persist in time after a single vaccination with the conjugate MenC vaccine?

- Despite decline of antibody concentrations in the years after vaccination, do memory B-cells persist?

- Antibody kinetics, it is important to follow the rise of antibody titers after vaccination:

o How long will it take before serum IgG antibodies are detectable and/or rise after primary- or booster vaccination?

o What is the avidity of serum IgG antibodies compared to the primary and booster vaccination?

- In what time period after primary vaccination with MenC are memory B-cells formed and how rapidly do memory B-cells expand after booster vaccination?

- Are there differences (antibody titer levels, IgG subclass distribution and serum antibody avidity) in booster responses between a booster vaccination using the conjugate MenC vaccine or plain serogroup C capsular polysaccharide .

Study description

Background summary

We will evaluate the kinetics of circulating antibodies, investigating the

presence of MenC specific plasma and memory B lymphocytes and antibody

production after polyclonal stimulation of peripheral blood mononuclear

cells (PBMC) in vitro. Vaccine responses after a single or multiple MenC

vaccinations (booster with MenC conjugate or with polysaccharide vaccine)

will be compared with natural immunity without previous vaccinations. It

will be interesting to investigate if the polysaccharide vaccine is capable

of inducing a booster response. And if so, it will be of interest to

characterize this response and compare it to the booster response induced

by the conjugate vaccine.

Study objective

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 design

Study Calendar:

Day 0: Pre-vaccination blood sample (20-30ml)

Day 0: Vaccination with MenC conjugate vaccine or Men(A)C polysaccharide vaccine

Day 1: Blood sampling (20-30ml)

Day 3: Blood sampling (20-30ml)

Day 5: Blood sampling (20-30ml)

Day 7: Blood sampling (20-30ml)

Day 9: Blood sampling (20-30ml)

Day 11: Blood sampling (20-30ml)

Day 14: Blood sampling (20-30ml)

Day 28: Blood sampling (20-30ml)

Intervention

- One group receives a primary MenC conjugate vaccination (Neisvac-C).

- The other two groups receive either a conjugate MenC (Neisvac-C) or polysaccharide MenC

booster vaccination (Meningovax A+C).

Blood will be drawn before and several time points after vaccination.

Contacts

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Eligibility criteria

Inclusion criteria

1. Good general health;

2. Provision of written informed consent;

3. Adherent to protocol, and available during the study period

Exclusion criteria

1. Severe acute (infectious) illness of fever (>38.5°C) within 2 weeks before vaccination;

2. Present evidence of serious disease(s) demanding medical treatment that might interfere the results of the study;

3. Known or suspected allergy to any of the vaccine components (by medical history);

4. Known or suspected immune deficiency;

5. History of any neurologic disorder, including epilepsy;

6. Previous administration of plasma products (including immunoglobulins) within the last 6 months;

7. Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2007
Enrollment:	21
Type:	Actual

Ethics review

Positive opinion

Date:	25-08-2008
Application type:	First submission

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
NTR-new	NL1359
NTR-old	NTR1419
Other	Laboratory for Vaccine Preventable Diseases (LTR) : LTR138
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A