Q-koorts post-vaccination study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28463

Source
Nationaal Trial Register

Health condition

Q-fever infection;
post-vaccination;
humoral immune response;
cellular immune response.

Sponsors and support

Primary sponsor: Rijks Instituut voor Volksgezondheid en Milieu (RIVM)
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Humoral immune response: IgG and IgM antibodies against fase 1 and 2 antigens of C. burnetii are measured by means of several serological tests:

1. Immune fluorescence assay (IFA);

2. Enzyme-linked immuno sorbent assay (ELISA);

3. Complement binding reaction (CBR);

4. Polymerase chain reaction (PCR);

5. Micro-array.

Cellular immune response: After stimulation of whole blood, the levels of interferon-gamma (IFN-gamma), interleukine (IL)-10 and possibly IL-12 production are measured. Also a T-helper 1 and T-helper 2 cytokine profile are measured in isolated mononuclear cells, isolated CD14+ monocytes and isolated T-cells after stimulation, and differentiation of the cells is studied.

Secondary outcome

N/A

Study description

Background summary

In The Netherlands, an unique population is vaccinated against Q-fever, namely people with risk factors for a complicated course of a Q-fever infection. In this study the humoral and cellular immune response is compared in 3 groups: vaccinated people, people screened for but not vaccinated due to serologic profile showing previous Q-fever infection, and people screened for but not vaccinated due to serologic profile showing a chronic Q-fever infection. The groups are also compared with a group of naturally infected people for which similar data have been already collected.

Study objective

To gain insight in the humoral and cellular immune response against Coxiella burnetii of people with risk factors for chronic Q-fever infection who are either vaccinated or have experienced a natural infection or have a chronic infection.

Study design

4, 8, and 12 months after vaccination (vaccination program took place prior to this study).

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Has taken part in the national Q-fever vaccination program;

2. Willing to adhere to blood draw schedule;

3. Signed Informed Consent.

Exclusion criteria

None.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2011
Enrollment:	280
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-06-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35763
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2812
NTR-old	NTR2953
CCMO	NL36319.000.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35763

Study results

Summary results
N/A