Q-koorts post-vaccination study.

Gepubliceerd: 24-06-2011 Laatst bijgewerkt: 19-03-2025

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28463

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Rijks Instituut voor Volksgezondheid en Milieu (RIVM)
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. Willing to adhere to blood draw schedule;

3. Signed Informed Consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel

Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2011
Aantal proefpersonen:	280
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-06-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35763
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A