Q-fever post-vaccination study

Published: 24-05-2011
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To gain insight in the humoral and cellular immune response of people with risk factors for chronic Q-fever after vaccination against Q-fever and of people who have had a natural infection or have a chronic infection.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON35763

Source
ToetsingOnline

Brief title
Q-fever post-vaccination study

Condition

- Bacterial infectious disorders

Synonym
Coxiella burnetii infection, Q-fever

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: cellular immune response, humoral immune response, post-vaccination, Q-fever

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:: immune fluorescence assay (IFA), enzyme-linked immuno sorbent assay (ELISA), complement binding reaction (CBR), polymerase chain reaction (PCR) and 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

not applicable

Study description

Background summary

Currently a Q-fever vaccination campaign is ongoing in The Netherlands for people with an increased risk of a serious course or the chronic form of Q-fever after infection with Coxiella burnetii. The risk factors are some vascular disorders and heart valve disorders. The gevaccinated population in The Netherlands is unique in the world; the Q-fever vaccine is used in Australia in youngm helathy people without prior exposure to C. burnetii. In a population with the mentioned risk the humoral or cellular immune responses are unknown. Besides that it is unknown whether there are in the immune responses between vaccinated people and those who have had a natural infection.

Study objective

To gain insight in the humoral and cellular immune response of people with risk factors for chronic Q-fever after vaccination against Q-fever and of people who have had a natural infection or have a chronic infection.

Study design

Observational study without intervention with invasive measurements (2 blood draws). Three blood tubes (30 ml) will be drawn at 6 months and 12 months after vaccination (or after a positive result of serological screening of skin test) and a short questionnaire will be answered. The blood draw will be combined with a regular visit at the outpatient clinic of the participant. If this is not possible within 3 weeks prior to or after the planned date, the blood drawal will be done at the participant's home.

Study burden and risks

The burden for the participants of this study is judged as low. The potential risks of venapunction is possibly local pain or a haematoma and is considered negligible.

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

- Signed Informed Consent
- willing to adhere to blood draw schedule
- has taken part in the national Q-fever vaccination campaign

Exclusion criteria

none

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-08-2011
Enrollment:	400
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Q-VAX Q-fever vaccine and skin test

Ethics review

Approved WMO Date:	24-05-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	31-05-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-03-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-03-2012
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

ID: 28463
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2011-001401-28-NL
CCMO	NL36319.000.11
OMON	NL-OMON28463