Effect of Coxiella burnetii infection on health status of patients following an outbreak of Q fever.

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To determine the health status of the patients of the Q fever outbreak in the Netherlands in 2007, one year after primary Q fever infection.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Rickettsial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32794

Source
ToetsingOnline

Brief title
Health status after Q fever.

Condition

- Rickettsial infectious disorders
- Respiratory tract infections

Synonym
Coxiella burneti infection, Query fever

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Coxiella burnetii, Health status, Outbreak, Q fever

Outcome measures

Primary outcome

Health status in patients one year after primary Q fever infection, as compared

to age and sex matched controls.

Secondary outcome

N/A

Study description

Background summary

In 2007, a possibly goat-related Q fever outbreak of 73 cases was identified in the Netherlands [1]. During clinical and serological follow-up of this cohort, a striking incapacitating and protracted fatigue lasting more than 6 months after primary Q fever infection was noted in about one third of patients. In the literature, research groups from England [2-4], Australia [5] and Canada [6] have reported similar findings and a marked reduced quality of life in patients after Q fever outbreaks. In the Netherlands, no data exist on the impact on long term health status after acute Q fever.

Study objective

To determine the health status of the patients of the Q fever outbreak in the Netherlands in 2007, one year after primary Q fever infection.

Study design

The health status of the patients from the 2007 Q fever outbreak will be assessed using of the Nijmegen Clinical Screening Instrument (NCSI). This is a compilation of a well validated, evidence based battery of instruments for detailed measurement of health status [7].
As controls, Q fever patients are asked to bring along an age and sex matched *buddy* from their neighbourhood, without a history of Q fever. The controls will be serologically tested for Q fever.

Study burden and risks

Taking the patients questionnaire and determining serological Q fever status in the Q fever group can be considerd part of routine medical care. Controls are subjected to a single venous blood sampling for serological testing for Q fever and asked to fill out the NCSI. Results of this investigation will answer the question whether there really is a long term, Q fever related, decline in health status in this first ever Dutch Q fever outbreak cohort. As the incidence of Q fever is likely to increase in the Netherlands in the years to come, this could lead to an hightened awareness of this chronic sequel after primary Q fever and better health care for this group of patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Serologically proven Q fever infection during the Q fever outbreak in 2007.

Exclusion criteria

None for the Q fever group. Positive Q fever serology for the control group.

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-04-2011
Enrollment:	146
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL24404.091.08