Understanding Q-detect: Coxiella burnetii exposure and the humoral and cellular immune response

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(i) to determine specificity of Q-detect* for registration purposes. (ii) to design a decision tree for follow-up of patients with a positive Q-detect* and

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

Summary

ID

NL-OMON41033

Source
ToetsingOnline

Brief title
Understanding Q-detect(TM)

Condition

- Bacterial infectious disorders

Synonym
Coxiella burnetii infection, Q-fever

Research involving
Human

Sponsors and support

Primary sponsor: Innatoss Laboratories BV
Source(s) of monetary or material Support: Innatoss

Intervention

Keyword: IGRA, Q-detect, Q-fever, Specificity

Outcome measures

Primary outcome

Percentage Q-detect positive individuals in a low incidence region

Secondary outcome

Definition of a cytokine and antibody profile of Q-detect* positive individuals

in comparison to known Q fever patients.

Study description

Background summary

Between 2007 and 2011 a large Q fever epidemic struck the Netherlands. Many people still suffer from chronic disease that damages vessels and heart valves. Other are suffering from long-term complaints such as chronic fatigue, myalgia, arthritis and general malaise. To diagnose Q fever, serology is the main method available in the clinic. Antibodies are often no longer measurable in people with a past infection.
The Coxiella Induced Interferon-gamma test (Q-detect*) was designed at the Radboudumc (Nijmegen) and further developed at Innatoss, The test was used in a large study in Herpen. In the Q-Herpen-II study 1517 villagers were tested for Q fever. The aim of the study was (i) early identification of chronic Q fever patients and (ii) determining the prevalence of Q fever in a high incidence area. One of the secondary aims was to compare Q-detect* with the indirect immune fluorescence (IFA) test. In light of waning immunity, the hypothesis was that a cellular immunity test could identify additional cases on top of measuring antibodies.
This hypothesis was confirmed. On top of 461 individuals positive in IFA and Q-detect*, 36 were positive in IFA only and 402 individuals were positive in Q-detect* only. The discrepancy between the two laboratory tests was unexpected. This triggered questions on specificity of Q-detect*. In the current study we address this issue, in part to provide an answer to the 402 individuals that were only Q-detect positive and also to define specificity and sensitivity of Q-detect*.

Study objective

(i) to determine specificity of Q-detect* for registration purposes.
(ii) to design a decision tree for follow-up of patients with a positive Q-detect* and

Study design

A random group (n=100) from a Dutch region minimally affected by Q fever will be tested in Q-detect*, which measures the interferon-gamma production ex vivo in whole blood after stimulation with heat-killed Coxiella burnetii (C.b.). C.b. is cultured and processed at the Central Veterinary Institute in Lelystad. Positive samples will be tested for anti-phase 1 and anti-phase 2 Coxiella antibodies using indirect immune fluorescence (IFA). IFA-negative samples will be tested in an in-house developed immunoblot that identifies antibodies against different C.b. antigens. For comparison, 25 individuals with a history of Q fever (IFA and Q-detect* positive), will be tested in the immunoblot as well as cytokine test, that measures IFN-gamma as well as TNFalpha, IL1beta, IL-2, and IL-10. The working hypothesis is that infected individuals will resemble Q fever patients in immunoblot as well as cytokine profile.

Study burden and risks

Random participants donate one additional tube of blood (4 mL). The venepuncture is performed by qualified personnel of Medlon and poses negligible risk. Receiving information on the study and filling in the informed consent form will take not more than 10 minutes.
Q-fever patients are informed in advance by Innatoss and will need to visit the blood drawing post in Oss once. The venepuncture is performed by qualified personnel of DC Bernhoven and poses negligible risk.

Personal benefit is negligible but participation will contribute to providing better diagnostic options for Q-fever.

In the event that subjects have a positive Q-detect test (either true positive or false positive) Innatoss will arrange for initial follow-up consisting of a standard IFA test. In the extremely rare event that blood tests suggest possible chronic Q fever, the GP will be informed immediately. The benefit for the subject is that a timely diagnosis will facilitate adequate treatment.

Subjects who are positive in IFA without an indication of possible chronic Q fever, will be notified through Medlon after the end of the study. If the results of the study indicate that the likelihood is high that a positive result is false positive, subject will be informed. At the request of the subject his/her GP will be informed as well. The independent expert (a GP with extensive Q fever experience) will provide professional advise.

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

Healthy volunteers: random group
Patients: known Q fever infection in past or present

Exclusion criteria

Healthy volunteers: history of Q-fever
All: presence of active infection, HIV, Hepatitis, blood-borne disease (all based on knowledge of subject)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2014
Enrollment:	125
Type:	Actual

Ethics review

Approved WMO

Date:	28-10-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL50415.028.14