T cell Response in Q fever (TRIQ-study)

Published: 23-05-2011
Last updated: 20-06-2024

Primary Objective: To determine T cell response to Coxiella burnetii antigens using an ELISPOT interferon gamma release assay in patients with different clinical outcomes after acute Q fever

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

Summary

ID

NL-OMON35925

Source
ToetsingOnline

Brief title
TRIQ-study

Condition

- Rickettsial infectious disorders

Synonym
Q fever

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Elispot, Q fever, T cell response

Outcome measures

Primary outcome

Results of the Coxiella ELISPOT assay for the different Q fever outcome groups.

Secondary outcome

N/A

Study description

Background summary

Q fever is an emerging zoonosis in the Netherlands with more than 4000 human cases since 2007. Acute disease is followed by clinical resolution in the majority of cases, 1-5% of patients progresses to chronic disease and 10-20% will exhibit the post-Q fever fatigue syndrome (QFS). Little is known about the pathophysiological mechanisms underlying these different clinical outcome states and current diagnostic tests measuring the humoral immune response (CFT, IFA, ELISA) to Coxiella burnetii infection have considerable limitations in accurately diagnosing these clinical outcome states. For example, diagnosing QFS relies solely on patients symptoms, as serological results do not differ from those asymptomatic after reconvalescence. Furthermore, establishing a diagnosis of chronic Q fever can be quite challenging due to lack of validated cut-off values for commercially available serodiagnostic tests. A recently developed paradigm postulates clinical outcome after Coxiella burnetii infection to be dependent on host-immunity/pathogen interaction. In this pathophysiological model, strong emphasis is given to persistence of Coxiella antigens in the host (as viable Coxiella bacteria in case of chronic disease, or remnant coxiella antigens in QFS), and dysfunctional host cellular immunity. T-cell mediated cellular immunity has a pivotal role in dealing with primary Coxiella burnetii infection and subsequent clearance or control of the bacterium in the host. Therefore, determining T-cell responses in Q fever patients can provide insights into the pathogenesis of the different Coxiella burnetii infection clinical outcomes. Furthermore, such a test may aid the clinician in accurately diagnosing the outcome of a Q fever infection and might be useful in guiding therapeutic interventions.

Study objective

Primary Objective:
To determine T cell response to Coxiella burnetii antigens using an ELISPOT

interferon gamma release assay in patients with different clinical outcomes after acute Q fever

Study design

Descriptive study, evaluation of a new diagnostic test.

Study burden and risks

Both volunteers and Q fever patients will undergo a full history and physical examination, fill out a questionnaire and will be subjected to a single blood sampling. No specific risks are associated with any aspect of the study.

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

-history of Q fever =/> 6 months: clinically compatible illness with serologically proven Coxiella burnetii infection.
-10 Q fever patients, no sequelae
-10 QFS patients (diagnosis: CFS as diagnosed using the 1994 CDC criteria)
-10 chronic Q fever patients
-10 seronegative controls
-informed consent

Exclusion criteria

- clinically significant co-morbidity (not for chronic Q fever patients)
- immunosuppressive medication
- < 18 years

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):	24-11-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	23-05-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-12-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL35867.100.11