Chronic Q fever in abdominal aortic disease

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

Summary

ID

NL-OMON46120

Source
ToetsingOnline

Brief title
QAAD

Condition

- Bacterial infectious disorders
- Aneurysms and artery dissections

Synonym
aneurysm, chronic Q fever, vascular prosthesis

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: Aneurysm, Chronic Q fever, Coxiella burnetii, Vascular prosthesis

Outcome measures

Primary outcome

Primary outcome: incidence of chronic Q fever and seronegativity

Secondary outcome

Secundary outcome: evaluate possible risk factors for developing chronic Q

fever by comparing seronegative patients and remaining seropositive patients

with chronic Q fever patients.

Study description

Background summary

After the Q fever outbreak in The Netherlands, approximately >40.000 people were infected with Coxiella burnetii, the bacterium that causes Q fever. Of these, more than 500 patients developed chronic Q fever. Chronic Q fever is a life-threatening disease which infects the vascular walls, vascular prosthesis and heart valves. Risk factors for developing chronic Q fever are a history of aneurysm or vascular prosthesis. After the outbreak, patients with an aneurysm or vascular prosthesis of the abdominal aorta were serologically screened for C. burnetii. Now, ten years after the start of the Q fever outbreak, we would like to complete follow-up of these patients. It is known that chronic Q fever can develop for years after the initial infection. Every year, new patients are diagnosed with chronic Q fever. Chronic Q fever knows a diagnostic delay, resulting in patients being diagnosed with already serious complications. Therefore, mortality rates among chronic Q fever patients are high.

Study objective

The objective of this study is to determine the incidence of chronic Q fever and seronegativity in vascular patients that were seropositive after the Dutch Q fever outbreak. Seropositivity can indicate a past resolved Q fever infection or chronic Q fever infection. These prevalences can also be used in the decision for a national screening programme.

Study design

Follow-up will be done by measuring the phase I and II IgG antigens against Coxiella burnetii in serum. Vascular patients that were already seropositive have an indication for follow-up of their serology, but vascular patients that became seronegative will be screened in the context of this study. Patients will be recruited by the treating vascular surgeon. First, they will receive an invitation letter via the post or during an appointment at the outpatient clinic. After receiving this letter, Bianca Buijs or a representative will contact the patient by telephone to ask if they would like to participate in the study. Informed consent will then be obtained and an appointment for venepuncture will be made. Patients who declined informed consent the first time will not be approached again.

Study burden and risks

One venepuncture will be perfomed for measurement of phase I and II IgG antigens against Coxiella burnetii. If serology indicates a possible chronic Q fever infection, we will refer patients to a infectious disease specialist for additional testing and, if necessary, treatment.

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

Patients with an aortic aneurysm (>30 mm), iliac aneurysm (>12mm) or central vascular reconstruction (such as EVAR op open reconstruction)
aged 18 years or older

Exclusion criteria

No informed consent obtained
Legal incapability

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2018
Enrollment:	162
Type:	Actual

Ethics review

Approved WMO Date:	17-10-2018
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	NL67239.028.18

Study results

Date completed:	01-07-2019
Actual enrolment:	46