Pilot study to evaluate the potential value of Fluorescence In Situ Hybridization (FISH) of white blood cells for the diagnosis of Q fever fatigue syndrome

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To evaluate whether Fluorescence In Situ Hybridization (FISH) on blood cells can distinguish patients with QFS from controls with no evidence of past Coxiella exposure and individuals with past asymptomatic C. burnetii infection.

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

Summary

ID

NL-OMON52417

Source
ToetsingOnline

Brief title
Evaluation of FISH as a diagnostic tool for Q fever fatigue syndrome

Condition

- Bacterial infectious disorders

Synonym
Q fever; Coxiellosis

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Q-support
Source(s) of monetary or material Support: Stichting Q-support

Intervention

Keyword: Coxiella burnetii, diagnostic, Fluorescence In Situ Hybridization, Q fever fatigue syndrome

Outcome measures

Primary outcome

Categorical FISH result (positive or negative, based on a pre-established

cut-off of 5% positivity (3/50) among counted leukocytes).

Secondary outcome

Percentage of positively scored leukocytes per blood sample and fluorescent

intensity of positively scored leukocytes.

Study description

Background summary

Q fever fatigue syndrome (QFS) affects approximately one in five patients following symptomatic acute infection with Coxiella burnetii. Diagnosis of QFS is complicated and criteria include a proven prior Q fever infection and exclusion of other fatigue-associated somatic or psychiatric disorders or chronic Q fever. Recently a preliminary report was published observing higher levels of C. burnetii 16S rRNA in white blood cells of QFS patients compared to healthy controls using a Fluorescence In Situ Hybridization (FISH) based test. To be of potential value as a diagnostic tool for QFS, this test needs to be able to clearly distinguish QFS patients not only from unexposed controls, but also from individuals with a past asymptomatic infection and no subsequent clinical sequelae.

Study objective

To evaluate whether Fluorescence In Situ Hybridization (FISH) on blood cells can distinguish patients with QFS from controls with no evidence of past

Coxiella exposure and individuals with past asymptomatic C. burnetii infection.

Study design

Forty-five subjects with known exposure history and clinical Q fever status will be recruited for this single site observational case-control pilot study. To ensure correct assignment of study groups, subjects recruited into groups A and B will be asked to provide information on any relevant major changes in their health status since 2014 that would pose a risk for the development of chronic Q fever or OFS. Subjects recruited for group D will be asked for consent to contact their treating physician to clarify they meet all criteria for proven chronic Q fever. After inclusion, blood will be collected by venipuncture at a single time point (max. 12 mL EDTA/lithium heparin blood and 8.5 mL serum). Per subject, two duplicate tubes of blood will be collected for FISH analysis. The test laboratory will be blinded to the assessment of duplicates and the (group) identity of subjects.

Study burden and risks

Venipunctures are performed by trained phlebotomists and pose a negligible risk. Participation will require a one-time visit of max. 20 minutes. There are no other procedures or follow-up after the specimens are obtained. Benefits for subjects from group A include an additional measurement of their Q fever exposure status (by IFA and IGRA). Participating individuals from group B, C and D have no added benefit from the FISH test performed, since it is not a validated diagnostic assay and their clinical status (past asymptomatic Q fever infection; diagnosis of QFS or chronic Q fever) is already known to them.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- At least 18 years old;
- Able and willing to sign the informed consent form;
- Known clinical Q fever history (absent for group A and B; Q fever fatigue syndrome for group C; proven chronic Q fever for group D);
- Previous positive test for serological response to Coxiella burnetii (group B-D) and negative serological and cellular response to Coxiella burnetii for group A.

Exclusion criteria

There are no specific criteria for subjects to be excluded from participation in this study, as long as they adhere to the inclusion criteria mentioned above.

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):	30-09-2020
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	14-09-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-06-2022
Application type:	Amendment
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	NL72640.028.20

Study results

Date completed:	31-07-2022
Actual enrolment:	49