Interferon gamma release assays for Q fever: Evaluation of new test formats in exposure screening to C. burnetii

Published: 14-09-2020
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The objective of the current study is to evaluate the performance of two new formats of the IGRA using pre-filled antigen formulations in a cohort of Dutch individuals with known prior exposure to Cb.

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

Summary

ID

NL-OMON52198

Source
ToetsingOnline

Brief title
Q-detect 2.0: Evaluation of new test formats

Condition

- Bacterial infectious disorders

Synonym
Q fever; Coxielliosis

Research involving
Human

Sponsors and support

Primary sponsor: Massachusetts General Hospital
Source(s) of monetary or material Support: Defense Threat Reduction Agency (DTRA;onderdeel van het ministerie van defensie van de VS). Innatoss is subcontractor van

Massachusetts General Hospital.

Intervention

Keyword: Coxiella burnetii, Diagnostic, Interferon gamma release assay, Q fever

Outcome measures

Primary outcome

Background-corrected Cb-specific IFNgamma production in the different test formats, and percentage of IGRA+ individuals in the different test formats based on pre-established cut-offs.

Secondary outcome

Background-corrected Cb-specific production of mediators induced down-stream of IFNgamma.

Study description

Background summary

The highly infectious coccobacillus Coxiella burnetii (Cb) is the causative agent of both acute and chronic Q fever disease in humans. Vaccination using an inactivated whole cell vaccine requires screening for prior exposure to Cb to mitigate adverse reactions to vaccination, but the combination of current pre-screening measures (serology and skin-prick test) is time consuming and insufficiently sensitive. Prior studies indicate that cytokine release by circulating immune cells in response to heat-killed whole cell Cb antigen (IFNgamma release assay, IGRA) is a more sensitive tool to assess pre-existing immune responses to Cb. To improve the usability of the current IGRA in high-volume central laboratory settings and in remote/resource austere settings, two new formats using pre-filled antigen formulations in microtubes (stage 1 adaptation) and cartridges for stimulation directly at the point of blood collection (stage 2 adaptation) are being developed.

Study objective

The objective of the current study is to evaluate the performance of two new formats of the IGRA using pre-filled antigen formulations in a cohort of Dutch

individuals with known prior exposure to Cb.

Study design

Hundred-forty subjects with known exposure history and clinical Q fever status will be recruited for this single site observational study. All subjects will be asked to donate blood at least three, but no more than five times for the separate evaluation of each of the two new IGRA assay formats (all subjects) and the assessment of parameters such as batch-to-batch and run-to-run reproducibility and storage stability of the pre-filled antigen formulations (in subgroups of up to 10 individuals each).

Study burden and risks

Venipunctures are performed by trained phlebotomists and pose a negligible risk. Participation will require three to five visits of max. 20 minutes.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- At least 18 years old;
- Able and willing to sign the informed consent form;
- Coxiella IGRA testing previously performed at Innatoss as part of research or diagnostic activities

Exclusion criteria

There are no specific criteria for subjects to be excluded from participation in this study.

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):	29-09-2020
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	14-09-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	28-06-2022
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	NL74801.028.20

Study results

Results posted:	08-05-2023
Actual enrolment:	109

First publication
01-01-1900

URL result
URL
Type

ext
Naam
www.ncbi.nlm.nih.gov
URL