Point-of-care detection of Borrelia antibodies using Sofia 2 Lyme+ FIA: Comparison of finger-prick whole blood assay versus testing in serum or plasma

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

Summary

ID

NL-OMON49820

Source
ToetsingOnline

Brief title
Sofia 2 Lyme+ testing in finger-stick whole blood

Condition

- Bacterial infectious disorders

Synonym
Borrelia infection, Lyme disease

Research involving
Human

Sponsors and support

Primary sponsor: Quidel Corporation

Source(s) of monetary or material Support: Quidel Corporation

Intervention

Keyword: Diagnostics, Finger-stick, Lyme disease, Point-of-care test

Outcome measures

Primary outcome

Cut-off values and incubation time needed for the WB assay, performance of the

WB assay including sensitivity and specificity.

Secondary outcome

N/A

Study description

Background summary

Lyme disease is a systemic, tick-borne disease caused by the bacterium Borrelia burgdorferi. Diagnostic testing consists of serological assays in which antibodies against different Borrelia burgdorferi strains are detected. Sofia Lyme fluorescent immunoassay (FIA) has been developed in the US as a rapid point-of-care assay, in which anti-Borrelia IgG and IgM are measured simultaneously within 10 minutes in plasma or serum specimens. The Sofia Lyme FIA has been adapted for the European setting (EU version: Sofia 2 Lyme+), where additional pathogenic Borrelia strains are present. To improve the usability of Sofia 2 Lyme+ in near-patient environments, the assay needs to be adapted to antibody detection in finger-stick whole blood specimens. The hypothesis of the current study is that performance of the Sofia 2 Lyme+ whole blood (WB) FIA is not inferior compared to testing in serum or plasma specimens.

Study objective

This study consists of two subsequent phases, with different objectives. The first phase includes a technical, explorative part with the objective of determining appropriate cut-off values and incubation times for the Sofia 2 Lyme+ WB FIA compared to Sofia 2 Lyme+ testing with serum/plasma. Based on a comparable study that was done is the US for the American version of Sofia Lyme, the expectation is that the sample incubation time will be somewhat

longer for testing in whole blood (15 minutes instead of 10 minutes in the US) and that cut-off values will have to adjusted for both IgG and IgM antibody testing.

When the required technical adjustments have been implemented for the Sofia 2 Lyme+ WB FIA, the second phase of this study will start. The objective of this part is to assess the performance of the whole blood assay: sensitivity and specificity complared to the CE-marked Sofia 2 Lyme+ assay with serum/plasma. In this study, we consider a sensitivity and specificity of 95% acceptable for the whole blood assay. The whole blood assay should not lead to more than 5% false-positives or 5% false-negatives compared to testing in serum/plasma. Based on the previous comparison in the US between testing in whole blood versus serum/plasma we expect that Sofia 2 Lyme+ WB FIA is non-inferior to Sofia 2 Lyme+ testing with serum/plasma, when technical parameters of the test have been correctly adapted.

Study design

Matched finger-stick whole blood, serum, and plasma specimens will be collected to compare Sofia 2 Lyme+ WB test results to Sofia 2 Lyme+ (serum/plasma testing) and comparator method results (i.e. standard ELISA and immunoblots). The study will consist of two phases, starting with an exploratory phase to determine cut-off values and incubation time for the WB assay. Next, performance of the adapted WB assay will be validated in the second phase of the study, in which new matched specimens will be collected and tested.

Study burden and risks

Venipunctures and finger-stick blood draws 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.

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

- At least 18 years old;
- Previous Borrelia antibody testing performed at Innatoss, with known results;
- Able and willing to sign the informed consent form.

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

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-01-2020
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	01-11-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	10-03-2020
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	NL71120.028.19