Comparison of assays for Borrelia detection

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To investigate the diagnostic properties of Borrelia immunoblots from various manufacturers and compare the diagnostic properties of different bands, and to validate the diagnostic value of B. burgdorferi PCR on blood and urine.

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

Summary

ID

NL-OMON36027

Source
ToetsingOnline

Brief title
PLEASE Addendum

Condition

- Bacterial infectious disorders

Synonym
lyme borreliosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,producent Borrelia assays

Intervention

Keyword: Blood assay, Borrelia, Lyme

Outcome measures

Primary outcome

Diagnostic properties of the standard immunoblot used in the UMCN Medical Microbiology laboratory, the EUROLINE-WB: Anti-Borrelia (Whole Antigen plus VlsE), will be compared to RecomLine (Microgen) and antigen detection according to Multiplex Analysis for Flow Cytometry (SERION Multianalyt* Borrelia burgdorferi, Virion/Serion, Germany). In addition, the most commonly used Borrelia PCR in the Netherlands on blood and urine will be applied.

Secondary outcome

Besides immunoblot testing, serum samples of all participants will be screened as usual for the presence of Borrelia IgG and IgM antibodies by ELISA (Virion-Serion, Clinida Benelux BV).

Patients and controls complete the following questionnaires for evaluation of physical, psychological, cognitive and generic functioning at baseline:

• Medical Outcomes Study 36-item Short-form General Health Survey (SF-36)

• Fatigue subscale of Checklist Individual Strength (CIS)

• Cognitive Failure Questionnaire (CFQ)

• Hospital anxiety and depression score HADS (anxiety and depression)

Study description

Background summary

Current serological tests are hardly of any value for late Lyme disease or diagnosing PLD. The diagnostic tests currently available cannot exclude or confirm the diagnosis active persistent Lyme disease. Positive tests even without disease lead to high medical consumption. This hampers decision-making about antibiotic treatment and leads to much controversy about Lyme disease.

Study objective

To investigate the diagnostic properties of Borrelia immunoblots from various manufacturers and compare the diagnostic properties of different bands, and to validate the diagnostic value of B. burgdorferi PCR on blood and urine.

Study design

Observational open comparative laboratory and questionnaire study.

Study burden and risks

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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

The present study is an addendum to the PLEASE study. Patients in this addendum are derived from the PLEASE study, and subsequently the same inclusion criteria apply:
a. Males or non-pregnant, non-lactating females who are 18 years or older.
b. Women of child-bearing potential must agree to use contraception methods other than oral contraceptives during the study therapy period, since failure of oral contraceptives due to long-term antibiotic use has been described and doxycycline might be teratogenic.
c. Patients with presumed or proven PLD. In this study, clinical suspicion of PLD is defined as complaints of musculoskeletal pain, arthritis or arthralgia, neuralgia or sensory disturbances (such as paraesthesias or dysesthesias), neuropsychological or cognitive disorders, and persistent fatigue, that are:
(1) temporally related to an episode of erythema migrans or otherwise proven symptomatic Lyme disease (defined as within 4 months after erythema migrans as assessed by a physician, or positive biopsy, PCR, culture, intrathecal B. burgdorferi antibodies), OR
(2) accompanied by a positive B. burgdorferi IgG or IgM immunoblot (as defined by strict criteria in line with the European Union Concerted Action on Lyme Borreliosis (EUCALB) and manufacturer of the immunoblot; see appendix A), regardless of prior ELISA IgG/IgM screening results.
d. Subjects must sign a written informed consent form.;A matched healthy control is defined as:
a. An adult with the same gender as the index patient (if possible)
b. No more than 10 years difference in age
c. Residence in the same neighbourhood

Exclusion criteria

The present study is an addendum to the PLEASE study. Patients in this addendum are derived from the PLEASE study, and subsequently the same exclusion criteria apply:
a. Subjects with a known history of allergy or intolerance to tetracyclines, macrolides, hydroxychloroquine or ceftriaxone.
b. Subjects who have had more than 5 days of antimicrobial therapy with activity against B. burgdorferi within the previous 4 weeks.

c. Subjects with a presumed diagnosis of neuroborreliosis (CSF pleiocytosis or intrathecal antibody production) for which intravenous antimicrobial therapy is required.
d. Subjects with a known diagnosis of HIV-seropositivity or other immune disorders. (No HIV serologic testing is required for the study).
e. Subjects with positive syphilis serology or signs of other spirochetal diseases.
f. Subjects with moderate or severe liver disease defined as alkaline phosphatase, ALAT, or ASAT greater than 3 times upper limit of normal.
g. Subjects who are receiving and cannot discontinue cisapride, astemizole, terfenadine, barbiturates, phenytoin, or carbamazepine (the concentrations of these drugs may increase during claritromycin therapy and/or lead to reduced availability of doxycycline).
h. Subjects who are currently enrolled on other investigational drug trials or receiving investigational agents.
i. Subjects who have been previously randomized into this study.
j. Severe physical or psychiatric co-morbidity that interferes with participation in the study protocol, including previous medical diagnosis of rheumatic conditions, chronic fatigue syndrome or chronic pain conditions as well as insufficient command of the Dutch language.
k. Co-morbidity that could (partially) account for the symptoms of the subject (e.g. vitamin B12 deficiency, anemia, hypothyroidism).;Exclusion criteria healthy controls
a. Symptoms of PLD: i.e.musculoskeletal pain, arthritis, neuralgia or sensory disturbances (such as paraesthesias or dysesthesias), neuro-psychological or cognitive disorders and persistent fatigue.
b. History of erythema migrans or treatment for Lyme disease.

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:	Pending
Start date (anticipated):	01-03-2011
Enrollment:	150

Type:	Anticipated

Ethics review

Approved WMO Date:	03-05-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL35510.091.11