LymeProspect: longterm-effects of Lyme disease

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27509

Source
NTR

Brief title
LymeProspect

Health condition

Borrelia burgdorferi;

Ziekte van Lyme;

Teken-overdraagbare aandoening;

Lyme disease;

Tick-borne disease.

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

The main study endpoint is the severity of persisting symptoms in confirmed Lyme patients at follow-up, based upon validated symptom and disability questionnaires. The main study parameters are all microbiological, immunological, genetic, clinical, cognitive-behavioral, and epidemiological parameters measured during follow-up, which are associated with, or could predict development of, such persisting symptoms.

Secondary outcome

Secondary study parameters are all microbiological, immunological, genetic, clinical, cognitive-behavioral, and epidemiological parameters in unconfirmed Lyme patients with existing persisting symptoms, that are possibly similar to the determinants of such persisting symptoms that were identified in the confirmed Lyme patients.
Other study parameters are health status (quality of life), relevant co-morbidity and medication use.

Study description

Background summary

This is a prospective cohort study with a one-year follow-up, and a total duration of 4 years. We recruit two groups of patients: 1) Individuals ¡Ý18 yrs old with a confirmed diagnosis of previously untreated early localized or disseminated Lyme borreliosis, and 2) Individuals ¡Ý18 yrs old with an unconfirmed Lyme diagnosis in combination with existing persisting symptoms. Group 1 patients will be included before or just after start of treatment. Using questionnaires with norm scores from the population we will determine which patients develop persisting symptoms after treatment. At baseline and during follow up, we will take blood and skin samples, and record epidemiological, clinical and cognitive-behavioral characteristics.
By explaining the outcome ¡°persisting of symptoms¡± in a prediction model by all possible measured explanatory determinants (e.g. an aberrant immune response, cognitive-behavioral factors, or persistence of infection), we can assess explanations and risk factors for the development of persisting symptoms for individual patients.
The outcomes of group 1 will be compared with group 2 to identify similar mechanisms behind the persisting symptoms.
Countries of recruitment: The Netherlands.

Study objective

Around 5-20% of Lyme borreliosis patients report persisting symptoms, such as

musculoskeletal pain, neurocognitive symptoms and fatigue after treatment. It has been hypothesized that long-term persisting symptoms are related to microbiological factors (e.g. persistence of Borrelia infection or co-infection with other tick-borne pathogens), immunological factors (auto-inflammation or auto-immunity, e.g. due to genetic differences), clinical and/or epidemiological factors (e.g. late-start of treatment, severity of symptoms) or cognitive-behavioral factors. In the proposed study we will test all of these hypotheses, through a prospective follow-up of patients with early localized, early disseminated or late disseminated Lyme borreliosis.

Study design

EM patients included through Tekenradar.nl:

T=0, 2 weeks, 6 weeks, 3 months, 6 months, 9 months, 12 months.

Confirmed Lyme patients included through the Clinical Lyme Centers:

T=0, 10 days, 6 weeks, 3 months, 6 months, 9 months, 12 months.

Unconfirmed Lyme patients included through the Clinical Lyme centers:

T=0, 3 months, 6 months, 9 months, 12 months.

Intervention

none

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

Inclusion criteria are partly dependent on the patient group and the route of inclusion.

All patients:

- are 18 yrs and older.

EM patients included through Tekenradar.nl:

- report an EM at Tekenradar.nl with a diameter larger than 5 cm and that has been present for less than 3 months;

- have a confirmed (typical or atypical) EM diagnosed by their GP;

- have not yet started treatment for the EM at the moment of inclusion;

Confirmed Lyme patients included through the Clinical Lyme Centers:

- have a confirmed diagnosis of early or late Lyme borreliosis;

- have not yet started treatment at the moment of inclusion, or, for disseminated Lyme borreliosis cases, at most 1 week before inclusion.

Unconfirmed Lyme patients included through the Clinical Lyme centers:

- symptoms that are present at the time of inclusion and have persisted for more than 6 months, such as myalgia and arthralgia, neuralgia, concentration disorders and cognitive disturbances, with or without fatigue.

- have a history of an unconfirmed suspicion for Lyme disease based on a positive result of a non-recommended
diagnostic test OR onset of disease symptoms (as described above) that have started within one month after a documented tick bite;

-have a negative serological test for Borrelia spp.

Exclusion criteria

Exclusion criteria are partly dependent on patient group and route of inclusion.

All patients:

- are unable to give informed consent or do not have a thorough command of the Dutch language.

EM patients included through Tekenradar.nl:

-started treatment for erythema migrans before inclusion.

Confirmed Lyme patients included through the Clinical Lyme Centers:

- started treatment for erythema migrans before inclusion, or for disseminated Lyme borreliosis more than one week before inclusion.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2015
Enrollment:	2300
Type:	Actual

Ethics review

Positive opinion

Date:	13-02-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47035
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4744
NTR-old	NTR4998
CCMO	NL50227.094.14
OMON	NL-OMON47035

Study results