PLEASE5+ - Long-term outcomes and quality of life of patients with symptoms attributed to Lyme borreliosis

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21558

Source
NTR

Brief title
PLEASE5+

Health condition

Borrelia burgdorferi; Lyme disease; Lyme borreliosis; tick-borne disease; Post-treatment Lyme Disease Syndrome

Sponsors and support

Primary sponsor: Radboud university medical center, Nijmegen, the Netherlands
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The health-related quality of life 5-8 years after participation in the randomized controlled trial on the effect of prolonged antibiotic treatment on persistent symptoms attributed to

Lyme borreliosis (PLEASE).

Secondary outcome

- long-term impact of persistent symptoms attributed to Lyme borreliosis on (ability to) work and social costs;
- reported use of medical or complementary interventions or support after PLEASE participation, and their association with the course of symptoms, quality of life and ability to work.

Study description

Background summary

This study is a longitudinal follow-up study utilizing questionnaires, blood and urine sampling and – in selected subgroups – interviews and focus groups, among subjects who have participated 5-8 years ago in the randomized PLEASE trial (NL2362). The primary objective is to assess the long-term (5-8 years) quality of life in patients who previously participated in the placebo-controlled randomized controlled trial on the effect of prolonged antibiotic treatment on persistent symptoms attributed to Lyme borreliosis (PLEASE). The main secondary objectives are to investigate the long-term impact of persistent symptoms attributed to Lyme borreliosis on societal status and ability to work, to collect data on the additional medical or complementary care that patients have undergone after participation in PLEASE, and to correlate these data with their course of symptoms, quality of life and ability to work.

Study objective

Patients with persistent symptoms attributed to Lyme borreliosis report a substantial disease burden and a poor quality of life. Little is known about the long-term outcomes of patients with persistent symptoms attributed to Lyme borreliosis. The impact of these persistent symptoms on workability has not been investigated to date.
After completion of the study visits, many patients in the PLEASE cohort have followed other after long-term antibiotic treatment or complementary therapies.
We hypothesize that patients included in the PLEASE study may have ongoing symptoms during long-term follow-up, affecting their quality of life, workability and social costs. Furthermore, we hypothesize that specific interventions or supportive strategies that patients have undergone have an impact on long-term outcomes.

Study design

One time point, and in a subset of patients one or more additional time points for interviews and focus groups (upon additional consent).

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

Subjects who have been randomized into the PLEASE study and not have subsequently withdrawn informed consent for the PLEASE or PLEASE5+ study are eligible. Inclusion criteria for PLEASE were: persistent symptoms that were attributed to Lyme borreliosis, either temporally related within 4 months to a physician-confirmed episode of erythema migrans or otherwise proven symptomatic Lyme borreliosis manifestation (by positive biopsy, PCR, culture, or intrathecal antibody production); or with a positive B. burgdorferi IgG or IgM immunoblot.

Exclusion criteria

Subjects who have withdrawn informed consent to PLEASE participation, have not consented to receive PLEASE5+ study information, or who do not provide written informed consent to PLEASE5+ participation are excluded, as well as subjects who have died.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2020
Enrollment:	280
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 50085
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8224
CCMO	NL71890.091.20
OMON	NL-OMON50085

Study results