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

Gepubliceerd: 13-12-2019 Laatst bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21558

Bron
NTR

Verkorte titel
PLEASE5+

Aandoening

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

Ondersteuning

Primaire sponsor: Radboud university medical center, Nijmegen, the Netherlands
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Radboudumc
Hedwig Vrijmoeth

024-3610782

Wetenschappelijk

Radboudumc
Hedwig Vrijmoeth

024-3610782

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2020
Aantal proefpersonen:	280
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50085
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten