Prevalence of Lyme neuroborreliosis among patients with painful radiculopathy visiting a teaching hospital in a Lyme endemic region

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Primary objective:The study objective is to assess whether there is a difference in prevalence of positive Lyme serology in patients with painful radiculopathy with nerve root compression versus patients with painful radiculopathy without nerve root...

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

Summary

ID

NL-OMON51614

Source
ToetsingOnline

Brief title
Lymeradiculopathy

Condition

- Bacterial infectious disorders
- Central nervous system infections and inflammations

Synonym
Lyme disease; Lyme neuroborreliosis

Research involving
Human

Sponsors and support

Primary sponsor: Gelre Ziekenhuizen
Source(s) of monetary or material Support: Geen externe financiering buiten Gelre ziekenhuizen. Voor de helft van de serologische testen is interne subsidie verkregen vanuit de Wetenschappelijke Advies Raad en de andere helft wordt gefinancieerd door de afdeling Medische Microbiologie van Gelre ziekenhuizen.

Intervention

Keyword: Borrelia, Lyme neuroborreliosis, Lyme radiculitis, Radiculopathy

Outcome measures

Primary outcome

The primary study parameters are the result of Borrelia serology

(positive/negative) and the result of the MRI scan (yes/no nerve root

compression). Patients with positive Borrelia serology and no nerve root

compression will be offered a lumbar puncture to test for Lyme

neuroborreliosis.

Secondary outcome

-Differences in patient characteristics and additional symptoms of patients

with radiculopathy caused by Lyme neuroborreliosis versus patients with

radiculopathy due to nerve root compression.

Study description

Background summary

The Dutch guideline for Lyme borreliosis states that in patients with painful radiculopathy, serological testing is only indicated if the symptoms are not explained by nerve root compression on MRI and the patient remembers a tick bite or EM. Sometimes the EM is still present at physical examination, but it is also known that many patients with Lyme neuroborreliosis have not noticed either the tick bite or EM. Positive Borrelia serology in patients with

radiculopathy indicates cerebrospinal fluid examination. Lyme neuroborreliosis is defined as the presence of CSF pleocytosis and/or intrathecal IgM and/or IgG Borrelia-specific antibody production.

Although meningoradiculitis, with symptoms of painful radiculopathy is the most common presentation of early Lyme neuroborreliosis, it is unknown how often Lyme neuroborreliosis is the cause of painful radiculopathy in the absence of nerve root compression. A Danish study demonstrated that phycisians often not consider Lyme neuroborreliosis as a cause of painful radiculopathy, leading to treatment delay. Possibly, Lyme neuroborreliosis is currently underdiagnosed as a cause of painful radiculopathy. If a substantial number of patients with painful radiculopathy turns out to have positive Lyme serology, we advise to update the Lyme guidelines including standard serological testing for Lyme borreliosis in patients with painful radiculopathy.

Study objective

Primary objective:
The study objective is to assess whether there is a difference in prevalence of positive Lyme serology in patients with painful radiculopathy with nerve root compression versus patients with painful radiculopathy without nerve root compression.

Secondary objectives:
1. To assess the prevalence of Lyme neuroborreliosis in patients with painful radiculopathy without nerve root compression.
2. To assess a difference in patient characteristics (i.e. difference in type of pain, location pain, additional symptoms (headache/meningeal irritation), previous tick bite, previous EM, tick exposure activities, month of presentation) of patients with radiculopathy caused by Lyme neuroborreliosis versus patients with painful radiculopathy due to nerve root compression.

Study design

The design is an observational cross-sectional study among patients who are referred to the neurology outpatient clinic of Gelre hospitals for the indication of radiculopathy. All patients who undergo an MRI scan of (a part of) the spinal column for the suspected radiculopathy will be eligible for inclusion in the study.

In patients who are willing to participate, serology will be tested for Borrelia, irrespective of history of tick bite or history of EM. In case of positive Borrelia serology in the absence of nerve root compression on MRI, the patient will be offered a lumbar puncture for diagnosis of Lyme neuroborreliosis. If Lyme neuroborreliosis is diagnosed, the patient will be treated according to the guidelines. In case of negative Borrelia serology

within eight weeks of symptom onset, in the absence of nerve root compression, Borrelia serology will be tested again after eight weeks of symptom onset. If seroconversion occurs, a lumbar puncture will be offered.

Study burden and risks

Risk associated with participation are minimal, as a venipuncture is the only procedure patients will undergo. The benefit is that underdiagnosis of Lyme neuroborreliosis is unlikely and these patients receive timely and adequate treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- All patients visiting the neurology outpatient clinic of Gelre hospitals who undergo an MRI scan for the indication of painful radiculopathy
- 18 years or older
- Given informed consent for participation in the study

Exclusion criteria

- Patients who undergo an MRI scan for other reasons than radiculopathy
- Patients who have radiculopathy as a residual symptom after being adequately treated for Lyme neuroborreliosis
- Patients with a known other explanation for radiculopathy at time of referral, for example leptomeningeal metastasis or varicella zoster infection

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2022
Enrollment:	500
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-04-2022
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL79263.075.22