Lambert-Eaton myasthenic syndrome: Clinical characteristics, pathogenesis and tumour association

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- To study the clinical characteristics and disease course of patients with LEMS with or without SCLC- To identify the characteristics of the humoral or cellular immune response that are associated with the prolonged survival of patients with SCLC...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON40297

Source
ToetsingOnline

Brief title
LEMS and SCLC

Condition

- Autoimmune disorders
- Neuromuscular disorders
- Respiratory tract neoplasms

Synonym
LEMS

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: neuromusculair onderzoeksbudget LUMC (prof. dr. J.J.G.M. Verschuuren)

Intervention

Keyword: Lambert-Eaton myasthenic syndrome, paraneoplastic syndrome, Small cell lung cancer, tumour immunology

Outcome measures

Primary outcome

Description of epidemiology, clinical characteristics and disease course in

LEMS patients.

Comparison of the humoral and cellular immune response in LEMS patients and

SCLC patients with and without LEMS.

Secondary outcome

- Tumour size on lung imaging studies and growth rate upon follow-up.

- DELTA-P score tumor prediction score in LEMS patients, diagnosis of SCLC upon

follow-up

- Presence of other auto-antibodies possibly related to LEMS

- Tumour infiltration of SCLC by lymphocytes and macrophages (+- LEMS)

- Anti-tumour effect of serum VGCC antibodies and related macrophage and

adaptive response in vitro

- Presence of specific T cells against tumour-related antigens

- Patients' experience with symptomatic medication for LEMS

Study description

Background summary

A detailed description of clinical characteristics and disease course of patients with Lambert-Eaton myasthenic syndrome (LEMS) will enable earlier diagnosis and treatment of this rare, disabling, but well-treatable, neuromuscular disorder and the associated tumour This study will provide detailed knowledge about the immune response against voltage-gated calcium channels and the small cell lung cancer (SCLC) in patients with LEMS. This is essential for the development of future therapeutical interventions or immune-mediated therapies.

Study objective

- To study the clinical characteristics and disease course of patients with LEMS with or without SCLC
- To identify the characteristics of the humoral or cellular immune response that are associated with the prolonged survival of patients with SCLC and LEMS.

Study design

Single center prospective study

Study burden and risks

Patient burden and risk in this study will be minimal and mostly almost completely limited to the period shortly after inclusion. If a patient participates in all elements of the study this will include:
- detailed history and physical examination
- electromyogram to determine the severity of the LEMS
- blood donation. We will draw 90 mL at inclusion and up to 50 mL at follow-up for selected patients with SCLC.
Personal benefit would be the contact with the clinical researchers experienced in the treatment of this rare disorder, with the opportunity to be completely informed on all aspects of the disease and get detailed therapeutical advice.
At a group level the results will contribute to improved understanding of the pathogenesis, and possibly improved therapies.

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

Diagnosis of LEMS
Criterion 1 and 2 or 1 and 3 have to be fulfilled
1. Clinical features consistent with LEMS (proximal muscle weakness, reduced tendon reflexes, autonomic symptoms)
2. Abnormalities upon repetitive nerve stimulation (decrement of CMAP amplitude and/or increment after voluntary contraction or high frequency stimulation)
3. Presence of VGCC antibodies;Diagnosis of SCLC
Definitive diagnosis of SCLC based on pathology results (either cytology or histology).

Exclusion criteria

* Age < 18 years
* Unable to give informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-08-2013
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	02-08-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	17-03-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	22-05-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL44216.058.13