The effect of tetanus revaccination in patients with myasthenia gravis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON41984

Source
ToetsingOnline

Brief title
Tetanus revaccination in patients with myasthenia gravis

Condition

- Autoimmune disorders
- Neuromuscular disorders

Synonym
lambert-eaton myasthenic syndrome, LEMS, myasthenia, myasthenia gravis

Research involving
Human

Sponsors and support

Primary sponsor: Neurologie
Source(s) of monetary or material Support: Europese subsidie FP7

Intervention

Keyword: Myasthenia gravis, Revaccination, Tetanus

Outcome measures

Primary outcome

Raise in total tetanus specific tetanus serum IgG titer in patients with AChR MG, MuSK MG, or LEMS. A change in QMG composite score and MG ADL at 1 month after revacinnation .

Secondary outcome

Secondary endpoints are a change in the QMG, or QMG composite score and/or a changes in MG-ADL at 3 months after revaccination and a change in autoimmune antibody titers against AChR, MuSK or VGCC at 1 month after revaccination.

Study description

Background summary

Myasthenia gravis (MG) and Lambert-Eaton myasthenic syndrome are neuromuscular disorders in which functional acetylcholine receptors (AChR or MuSK) respectively voltage-gated calcium channels (VGCC) become depleted at neuromuscular junction due to an antibody-mediated autoimmune attack on the neuromuscular synapse. Patients are at an increased risk of infection due to the immunosuppressive therapy, while at the same time vaccination might be less effective. Despite the common use of immunosuppressive treatment in these patients, little is known about the effectiveness and safety of vaccination in these patients. Tetanus is a frequently used vaccine with a well know safety profile in healthy persons, but about the effectiveness and safety in myasthenic patients little is known. The expected side effects are redness at the injection site, muscle ache and fever. The side effects will be recorded during the study.

Study objective

The main objective of this study is to investigate the effectiveness of the humeral and cellular immune response after tetanus revaccination in patients

with AChR MG, MuSK MG, or LEMS. The secondary objective is to determine if revaccination induces immunological or clinical exacerbation in patients with AChR MG, MuSK MG, or LEMS

Study design

The study is a longitudinal experimental study. Blood samples and questionnaires will be used.

Intervention

The effect of the revaccination will be investigated by testing for tetanus specific serum IgG titer subclass, change in autoimmune antibody-titers and the tetanus specific T-cell immune response. Furthermore, the effect of treatment will be measured both objectively (Myasthenia Gravis Composite scale (MG composite)) and QMG) and subjectively (Myasthenia Gravis-Activities of Daily Living (MG-ADL) profile. The Quality of life questionnaire (MG-QOL15) will be validated. Adverse effects will be measured by a symptom questionnaire. Patients will continue to use their pre-study dose of pyridostigmine or prednisone or other immunosuppressive treatment throughout this study.

Study burden and risks

One week before the vaccination the patient will fill out the MG-QOL15 en SF-36 questionnaire at home. At the day of revaccination the patient will stay 4 hours at the hospital. Vital signs are measured after therevaccination. The MG composite, MG-ADL, SF-36 and MG-QOL15 questionnaire will be completed before the revaccination. All patients will fill in the symptom questionnaire 4 weeks after revaccination. At 4 weeks the patient will visit the hospital to draw a blood sample and fill out the MG-ADL, SF-36 and MG-QOL15 questionnaire. The MG composite en MG-ADL will be taken by the investigator. Three months after the revaccination the patient will fill in the MG-QOL15, SF-36 and MG-ADL questionnaire. Adverse effects of the revaccination include redness at the injection site, muscle ache and fever. These will be recorded and monitored throughout the trial.

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

Adult patients with myasthenia gravis or lambert eaton myasthenic syndrome based on a) clinical signs or symptoms suggestive of myasthenia gravis or lambert eaton (for example, slowly progressive fluctuating muscle weakness in specific muscle groups); and a positive serologic test for acetylcholine recepter (AChR) antibodies or muscle specific receptor tyrosine kinase antibodies (MuSK) or voltage-gated calcium channel antibodies (VGCC). b) patients with prednisone dose lower than 30mg and stable (dose +/-5mg) during the 3 months before participation; other immunosuppressive should be stable/unchanged. ;2. Males and females aged between 18 years and 65 years at the time of the injection.

Exclusion criteria

1. Received no previous tetanus vaccination in the childhood age or received a revaccination in de past year.
2. Myasthenic crisis in the last 3 months.
3. Presence of a thymoma or a planned thymectomy during the study period or within 12 months prior to the first dose of the tetanus toxoid booster immunization.
4. History or evidence of intravenous immunoglobulines or plasmapheresis within 3 months prior to the tetanus toxoid booster immunization.
5. Received a influenza vaccination 1 month before the tetanus revaccination.
6. The patient is unable to fill out the study questionnaires or be interviewed in Dutch, or is

unable to
7. The investigator can exclude patients for this trial which are deemed not suitable for any reason.
8. Use of vitamin K antagonist or the new oral coagulantia (NOACS)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-03-2015
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tetanusvaccin

Ethics review

Approved WMO Date:	16-02-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	11-03-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
EudraCT	EUCTR2014-004344-35-NL
CCMO	NL50993.058.14

Study results

Results posted: 29-10-2020

First publication
01-01-1900