Extensive Neurophysiological Investigation in Guillain-Barré patients, focussing on Motor unit Abnormalities and fatigue

Published: 18-04-2007
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To clarify the pathophysiological substrates of residual weakness and fatigue

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON30848

Source
ToetsingOnline

Brief title
ENIGMA-F

Condition

- Peripheral neuropathies

Synonym
GBS, Guillain-Barré syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Prinses Beatrix Fonds;stichting Nuts/ohra

Intervention

Keyword: Fatigue, Guillain-Barré syndrome, Motor Unit, Neurophysiology

Outcome measures

Primary outcome

Amount of MU reduction and changed MU recruitment.

Secondary outcome

-

Study description

Background summary

Guillain-Barré syndrome (GBS) is a severe post-infectious polyneuropathy. Its cardinal symptom is weakness. Recovery after GBS is usually slow and incomplete. Despite current treatments, 20% of GBS patients have a considerable residual handicap and most former patients experience weakness in addition to a severe and disabling form of fatigue. Somewhat surprisingly, these complaints are also common in clinically well recovered patients, who on conventional electrophysiological testing have a normal outcome. Until now, the exact mechanisms underlying the disabling fatigue and residual weakness have remained unclear. Preliminary evidence from our group suggests that both may result from reduced numbers of motor units (MUs). MUs are the functional units of the peripheral motor system, comprising a single alpha-motoneuron and the 20-2000 muscle fibers that this neuron innervates. Loss of MUs implies that the same amount of work (force generation) has to be performed with less MUs, with obvious consequences for weakness and fatigability. An alternative hypothesis is that reinnervation of denervated muscle fibers, a process that is inherent in the disease and subsequent recovery, may render previously small MUs large. Unintentional recruitment of these large MUs may then easily result in an overshoot of force. It is conceivable that the subsequent and ongoing compensatory mechanisms make extra demands on the muscle and on motor control that result in increased fatigue.

Study objective

To clarify the pathophysiological substrates of residual weakness and fatigue

Study design

In this study, 30 severely fatigued and 30 mildly fatigued patients with or without residual weakness will be recruited from our database of former GBS patients. All patients will undergo various assessments in a single session of approximately 3 hours: 1 hour for various scores, questionnaires, and a full neurological exam, and two hours for neurophysiological tests, particularly specialized electromyography (EMG) tests (collection of MU samples from electrically elicited and voluntary contractions). Control values will be collected in 30 healthy subjects.

Study burden and risks

The investigations are noninvasive. There are no risks, nor are there immediate benefits for individual patients.

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

*Age 18 years and older
*Residual fatigue after Guillain-Barré syndrome
*Written informed consent

Exclusion criteria

*severe other neurological or psychiatric disease
*Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and follow-up schedule. Judgment is up to the investigator

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-09-2007
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	18-04-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL16937.078.07