Extensive neurophysiological investigation in Guillain-Barré patients, focussing on motor unit abnormalities and weakness

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1)To determine the contribution of reversible dysfunction of nerve terminals to weakness 2) To identify electrophysiological patterns that improve classification of GBS patients, and that discriminate between patients with good and poor prognosis 3...

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

Summary

ID

NL-OMON31256

Source
ToetsingOnline

Brief title
ENIGMA-W

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

Intervention

Keyword: Clinical Neurophysiology, Guillain-Barré Syndrome, Motor Unit, Weakness

Outcome measures

Primary outcome

1) Change in motor units during the acute phase of the GBS.

2)Abnormalities in neurophysiological investigation (axonal vs demyelinating)

3)Existance of nerve terminal blocking

Secondary outcome

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Study description

Background summary

Guillain-Barré syndrome is a severe post-infectious polyneuropathy. Its cardinal symptom is weakness. Weakness is responsible for life-threatening complications in the acute phase and for residual disability. Unfortunately, in many patients current treatment options only have a modest effect. The development of more effective, targeted therapies requires improved understanding of GBS pathophysiology and refined classification of patients into pathophysiologically homogeneous subgroups. Despite its importance in GBS, the pathophysiology of weakness is only partly understood. We have evidence that indicates that the terminal axolemma and neuromuscular junction are involved in the acute phase of GBS in patients. GBS is currently classified in three subgroups. However, this simple classification of GBS patients is inadequate to understand the observed clinical heterogeneity that occurs within each of the subtypes. Some patients are only mildly affected and remain ambulant, while others have to be ventilated in an intensive care environment and may suffer lasting handicaps. Recovery and outcome are equally variable. More advanced electrophysiological techniques are now available (muscle scan, excitability testing, and multichannel recordings to improve insight in the pathophysiology of weakness in GBS, and to further classify GBS patients in electrodiagnostic and prognostic subgroups. We expect that at the end of the project, we further understand the pathofysiology of weakness and the working

mechanism of IVIg treatment and that we can better identify poor prognostic subgroups that may benefit from additional treatment in the future.

Study objective

1)To determine the contribution of reversible dysfunction of nerve terminals to weakness
2) To identify electrophysiological patterns that improve classification of GBS patients, and that discriminate between patients with good and poor prognosis
3) To clarify the pathophysiological substrates of residual weakness

Study design

observational, longitudinal study

Study burden and risks

The patients will have to undergo neurophysiological investigations. Except for the single fiber electromyography (SFEMG) (twice only), the investigations are non-invasive. There are no risks. During the first two weeks of admittance, the "scan"will be daily, more extensive neurophysiological testeing will be done once a week. After discharge at wk tests will be done at week 6, 13, 26, 52 and 104.

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
*In acute phase of 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 invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-02-2008
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	needle EMG (single fiber)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-01-2008
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	NL16875.078.07