T-cell response in CIDP, a biomarker study

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Our primary objective is to study the cellular immune response in CIDP during different stages of disease activity and to explore their role as a biomarker for treatment response and disease activity in patients with CIDP.

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

Summary

ID

NL-OMON40737

Source
ToetsingOnline

Brief title
Biomarkers in CIDP

Condition

- Peripheral neuropathies

Synonym
CIDP, inflammatory neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Prinses Beatrix Spierfonds

Intervention

Keyword: biomarkers, chronisch inflammatory demyelinating polyneuropathy, CIDP, T-cells

Outcome measures

Primary outcome

(1) the percentage of the total TCR repertoire representing dominantly expanded

T-cell clones,

(2) the number of circulating lymphocytes subsets and monocytes,

(3) the number of cell divisions during T-cell supression assays.

These paramters will be compared between groups of patients with active disease

and patients without active disease. In individual patients these parameters

will be compared during different states of disease activity.

Secondary outcome

Not applicable.

Study description

Background summary

CIDP is an inflammatory neuropathy in which the cellular immune response plays a major role. CIDP is a heterogeneous disease that responds variably to treatment and may follow different disease courses. Long-term treatment in CIDP is particularly challenging as it is accompanied with overtreatment in a significant number of patients and possibly undertreatment in others. Biomarkers of disease activity are lacking and urgently needed to guide maintenance treatment. In this study we will combine different methodological approaches to study the role of the cellular immune responses and to explore whether specific features of the cellular immune response can be used as a biomarker of disease activity.

Study objective

Our primary objective is to study the cellular immune response in CIDP during

different stages of disease activity and to explore their role as a biomarker for treatment response and disease activity in patients with CIDP.

Study design

Observational multicenter study.

Study burden and risks

The burden to subjects participating in this study is limited to a small number of study visits which largely overlaps subjects* standard care visit schedule. Subjects with CIDP remission will perform a single visit. In other participants blood sampling is performed two or three times, depending on their disease course.

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

- Newly diagnosed untreated patients who fulfill the clinical and electrophysiological EFNS/PNS criteria for CIDP OR
- Patients diagnosed with CIDP according to the clinical and electrophysiological EFNS/PNS criteria for CIDP with maintenance IVIg treatment (> 6 months of treatment) OR
- Patients diagnosed with CIDP according to the clinical and electrophysiological EFNS/PNS criteria for CIDP with a stable clinical condition without treatment in the last 12 months.
- Adult males or females (18 year or more)

Exclusion criteria

Lack of informed consent of the subject.

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:	Recruitment stopped
Start date (anticipated):	12-08-2014
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	11-06-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL49193.018.14