International CIDP Outcome Study A prospective study on clinical and biological predictors of disease course and outcome in CIDP

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

Summary

ID

NL-OMON44925

Source
ToetsingOnline

Brief title
ICOS

Condition

- Autoimmune disorders
- Peripheral neuropathies

Synonym
Chronic inflammatory demyelinating polyneuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: CSL Behring

Intervention

Keyword: Biological predictors, Chronic inflammatory demyelinating polyneuropathy, Clinical outcome, Prognostic models

Outcome measures

Primary outcome

ICOS will result in a combined data- and biobank of well defined patients with

CIDP.

The primary study parameters will include the grip strength measured by using a

Vigorimeter or Jamar dynamometer and the Rasch-MRC sum score. Furthermore we

will use several standardized validated clinical outcome measure scales such

as: Rasch-built Overall Disability Scale(R-ODS), modified INCAT sensory scale,

Pain Intensity Rating scale, Rasch-Fatigue Severity Scale(FSS) and EuroQoL-5D

questionnaire.

Secondary outcome

nvt

Study description

Background summary

Chronic inflammatory demyelinating polyneuropathy (CIDP) is a heterogeneous disorder with a highly variable clinical presentation. Patients differ greatly in clinical presentation and clinical course, where some patients develop an acute form of CIDP with a more rapidly progressive disease course while other patients have a slow progressive disease course and might need a long course of treatment. This may indicate the presence of distinct subtypes of CIDP.

Treatment response is also highly variable in CIDP patients, depending on pathogenesis and disease severity.
The aim of the study is treat CIDP patients with more individual therapy, this could only be possible if there are prognositc models that accurately predict the clinical course in individual patients. Ideally such models should be based on clinical and biological markers that are strongly associated with disease course. By identifying different subtypes of CIDP may lead to a more individualised and more effective treatment in CIDP patients.
Further research is requiered to define which determinants can be used to identify variation in clinical subtypes, clinical course, disease activity, response to treatment and disease outcome. To address these research questionos it is requiered to conduct a prospective study with standardized collection of clinical data and biomaterials from a large group of well defined CIDP patients during a long follow-up period.

Study objective

De lnternational CIDP Outcome Study (ICOS) aims to describe in detail the variation in clinical and electrophysiological subtypes, current practice of treatment, clinical course and outcom in CIDP. The second objective is to define the clinical and biological determinants and predictors of this variation in subtypes, disease activity, treatment response and outcome.

Study design

ICOS is a prospective observational international multi-centre study which will start with a pilot study in 3 Dutch neuromuscular centres. After the pilot phase, ICOS will expand to more neuromuscular centres in The Netherlands and to international centres. We aim to include at least 1000 CIDP patients en variants of CIDP. The study follow-up will be at least 2 years. The ICOS will result in the largest detailed and standardized databank with data about the variations in CIDP subtypes, clinical course, disease activity, treatment regimes, and diagnostics (serum samples, electrophysiology, cerebrospinal fluid and nerve tissue). Furthermore ICOS will result in a biobank where DNA and serum samples are collected.

Study burden and risks

Patients with a newly diagnosed CIDP will have more frequent hospital visits with venapunctures and physical examination, in the context of standard clinical care and medical work-up. Known CIDP patients are seen less frequent. The follow-up visits of ICOS are combined with the standard clinical care visits as much as possible.
Besides the standard clinical care we will also collect clinical data, questionnaires and blood samples at 4-8 moments. A venapuncture has a very small risk of formation of hematoma and infection. The majority of CIDP

patients will unidergo an EMG or a lumbar puncture as part of the stand diagnostic workup. Only in these patients, these data will be collected for the ICOS. If no lumbar punctore or EMG was performed for various reasons, no lumbar puncture will be performed in the scope of this study. When a lumbar puncture is performed, there is a possibility to collect additional 2 ml of CSF for further reasearch when the patient consents. Collection of these 2 ml extra results in no additional risks or discomfort for the patient. So for this study the risks are negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

1. The ICOS is using the EFNS/PNS criteria (clinical and electrophysiological criteria) for the diagnosis of CIDP.
Three categories of patients are eligible for the ICOS:
a) Patients fulfilling the clinical criteria and the definite, probable or possible electrophysiological criteria defined in supplement 1.
b) Patients fulfilling the clinical criteria and at least two supportive criteria defined in supplement 1.
c) Patients fulfilling the clinical criteria for pure sensory CIDP and at least two supportive criteria defined supplement 2 (if not fulfilling the electrophysiological criteria).
2. Being able and willing to conduct a follow-up of at least 2 years.
3. Informed consent.

Exclusion criteria

No exclusion criteria

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):	12-11-2015
Enrollment:	500
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	17-07-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-04-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-12-2024
Application type:	Amendment
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	NL52654.078.15