Chemotherapy induced peripheral neuropathy outcome measures standardisation study

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Primary Objective: To define a core set of measures that meet clinimetric properties for being simple, valid, and reliable in CIPN.Secondary objectives: To develop an Overall Disability Sum-Score (ODSS) specific to CIPN; To develop a Responsiveness...

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

Summary

ID

NL-OMON32417

Source
ToetsingOnline

Brief title
CI-Perinoms study

Condition

- Peripheral neuropathies

Synonym
peripheral nerve lesion, polyneuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: (poly)neuropathy, chemotherapy, clinimetry, outcome measures

Outcome measures

Primary outcome

Endpoints: The primary endpoint for this study is to determine the validity and reproducibility of the proposed outcome measures in chemotherapy-induced peripheral neuropathy.

Trial Treatments: There are no trial-specified treatments as subjects will receive only their usual medical care which must be stable during this study. The investigators will not influence decisions regarding treatment duration nor supply medication for this study.

Secondary outcome

not applicable

Study description

Background summary

The principal aim of this study is to evaluate through a multi-center international collaboration among experienced neurologists and oncologists the best method(s) available to assess and monitor chemotherapy-induced peripheral neuropathy (CIPN).
Comparison between physician evaluation and subjects* subjective report of CIPN severity using established questionnaires will be performed.

Study objective

Primary Objective: To define a core set of measures that meet clinimetric properties for being simple, valid, and reliable in CIPN.

Secondary objectives:
To develop an Overall Disability Sum-Score (ODSS) specific to CIPN;
To develop a Responsiveness study based on the results of this study.

Study design

To assess inter-observer, intra-observer and test-retest studies, two investigators in each participating centre will perform the selected impairment and activity limitation scales in study subjects. Electrophysiological studies will be performed only once at entry. One of the examiners will double-check the questionnaires and scales prior to the departure of the subject. Subjects will be examined at two different occasions at the outpatient clinics. During the first visit the two examiners will perform their scores independently and consecutively (usually within 2 hours) (inter-observer measures). Within 1-3 weeks, subjects will return for a second visit and both investigators will re-examine the subject (intra-observer values) without having access to previous examination findings. The outcome measures will be completed by the subjects for a second time (test-retest examination).

Statistical Methods: Based on external expert opinion, the number of subjects will be determined by a statistician using the current TNSc data and knowledge of the number of centers in the two studies.

Correlation (Validity) studies will be generally performed using the Spearman Rank correlation coefficient. In cases of multiple group analyses, one-way analyses of variance with corrections according to Bonferroni multiple-comparison tests will be performed. The Cronbach*s alpha coefficient will be estimated in multi-item scales (adequacy criterion > 0.7). Other reliability (test-retest, intra-observer, inter-observer) values for the various outcome measures will be quantified by estimation of the intra-class correlation coefficient using a one-way random effects analysis of variance model as co-variable, and the different outcome measures as independent variable.
Descriptive statistics will be used to summarize demographics and other variables of interest.

Study burden and risks

Patients will be examined at the outpatient clinic twice with an interval of 1-3 weeks. Patients will be asked to complete questionnaires. This will take about 1.5-2 hours per visit.

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

1. Subjects must have CIPN and be available for study at a participating centre. CIPN is defined as having symptoms, signs and/or test results that in the opinion of the Investigator are typical of a toxic polyneuropathy due to the subject*s chemotherapy.
2. Male and female subjects who are 18 years of age or older.
3. Subjects must give informed consent by signing and dating an informed consent form prior to study entry.
4. Subjects must be willing to complete all study-related activities and follow-up visits required by the protocol.
5. Subjects must have a stable clinical condition. A clinical stable condition is defined as either an unchanged clinical functionality as declared by the subject to the best of his/her knowledge over 1 month prior to the study or no clear objective changes at neurological examination by the researcher when compared with recorded findings over two month prior to study entry (if available).
6. Each subject will receive an information leaflet and an informed consent form. A common version will be prepared in English and translated by each investigator in its own language.

7. Subjects must have a Karnofsky performance score greater than or equal to 70.

Exclusion criteria

Subjects presenting with any of the following will not be included in the trial:
1. Active underlying malignancy and poor prognosis.
2. Chemotherapy is planned while the subject is in this study.
3. Concomitant diseases e.g., diabetes, renal insufficiency, alcohol abuse (more than 5 IU/day) that would interfere or complicate the assessments.
4. Concomitant neurologic conditions, e.g., brain tumor, spinal or brain metastases that would interfere or complicate the assessments.
5. Severe depression that in the opinion of the Investigator would complicate the assessments.
6. Chronic treatment with antiepileptic drugs, antidepressants and major analgesics, unless stable dosing and conditions have been reached.
7. Subjects with a known presence of peripheral nerve damage due to another illness or medication.
8. Subjects who are currently receiving another medication that has known potential to produce neurologic peripheral nerve toxicity, (e.g. metrodiazole or isoniazid).
9. Subjects with any other condition, which, in the investigator*s judgment might decrease the chance of obtaining satisfactory data to achieve the objectives of the study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2008
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-04-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-11-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-11-2011
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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	NL23064.068.08