Assessment of the responsiveness of the Rasch-built, CIPN-specific questionnaire (CIPN-RODS) to clinical changes in patients undergoing neurotoxic chemotherapy.

Published: 28-10-2015
Last updated: 19-04-2024

Primary Objective: to assess formally the responsiveness of a core set of measures derived from the previous CI-PeriNoms Study (Cavaletti, et al., 2013).Secondary objective: to test the responsiveness of the CIPN specific Rasch-built Overall...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON42804

Source
ToetsingOnline

Brief title
Assessment of the CIPN-RODS in patients undergoing neurotoxic chemotherapy.

Condition

- Miscellaneous and site unspecified neoplasms benign
- Peripheral neuropathies

Synonym
chemotherapy-induced polyneuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CIPN-RODS, neurotoxic chemotherapy, polyneuropathy, Rasch-built questionnaire

Outcome measures

Primary outcome

The NCI-CTC v4 Sensory: The National Cancer Institute Common Toxicity Criteria for Neuropathy sensory and motor has been the standard method of assessing sensory neuropathy in most Oncology and industry based studies of CIPN. This requires only a brief interview with the subject.

The Total Neuropathy Score© (TNS©): The TNS© is a composite neuropathy scale captures neurological physical assessment in a much broader way (range: 0 - 40) than oncological toxicity scales which usually range from 0 to 4 or 5.

The Douleur Neuropathique 4© (DN4©): The DN4© is one of the questionnaires that can be useful in diagnosing neuropathic pain.

The Functional Assessment of Cancer Therapy - Gynecologic Oncology Group Neurotoxicity© (FACT-GOG-NTX©): The FACT-GOG-NTX© is questionnaire to assess quality of life of patients being treated with neurotoxic chemotherapy drugs.

PI-NRS and PGIC: Although not commonly reported, pain has been demonstrated in

CIPN and therefore we will be examining the presence and dynamics of pain serially using the most frequently adopted simplistic scale, the Pain Intensity Numeric Rating 11-point Scale (PI-NRS). In addition, the 7-points patient reported global impression of change (PGIC) will also be registered (Farrar, et al., 2001).

CIPN-RODS: The responsiveness of the CIPN-RODS will also be examined (Binda, et al., 2013).

Electrophysiology: nerve conduction studies.

Secondary outcome

-

Study description

Background summary

Chemotherapy-induced peripheral neuropathy (CIPN) is a major and dose-limiting adverse event of a wide variety of chemotherapeutic agents including a number of agents in development. CIPN is generally characterized by distal symmetrical numbness, tingling, paresthesias, dysesthesias, pain and/or weakness which significantly impacts subjects* functionality and quality of life (Cavaletti and Zanna, 2002; Markman, 1996; Wenzel, et al., 2003). The incidence of CIPN may be as high as 100% in treated patients, depending on dose and dose-intensity of the chemotherapy regime. The neurotoxic side effects can be permanent, and treatment is usually difficult. Neuro-protective agents are now proposed that would either prevent or ameliorate CIPN without altering the therapeutic benefits of the chemotherapeutic agent used. However, prior to clinical trials of these agents, it is important to be able to assess CIPN in a simple, valid, and reproducible manner in accordance with postulated international guidelines (Hobart, et al., 1996; Streiner, 1998). Validity and reliability are considered the minimum requirements for outcome measures prior

to their use in assessing any particular medical condition.

Study objective

Primary Objective: to assess formally the responsiveness of a core set of measures derived from the previous CI-PeriNoms Study (Cavaletti, et al., 2013).

Secondary objective: to test the responsiveness of the CIPN specific Rasch-built Overall Disability Scale (CIPN-RODS) derived from the previous CI-PeriNoms study (Binda et al., 2013).

Study design

This is a longitudinal, international multi-center study.
The participant is expected to visit our hospital at least twice to undergo several tests (neurological examination, EMG, filling out questionnaires). The patient is expected for his first visit before the start of the chemotherapy. Neurological examination will be carried out and several questionnaires will be filled out. In addition, an EMG will be made. The second visit will take place at the moment that a polyneuropathy is noted by the treating physician. During this visit, only neurological examination and filling out the same questionnaires as the first visit will be performed. So, if the patient does not develop symptoms of polyneuropathy during the chemotherapeutic treatment, this second visit will not take place. The last visit is immediately after the end of the treatment with chemotherapy. Again, neurological examination will be performed and a number of questionnaires is asked to fill out by the participant. An EMG will also be performed.

Study burden and risks

All examinations (neurological examination, measurement of force / sense, the EMG and questionnaires) do not have special risks.

Contacts

Public
Selecteer

Oxfordlaan 10
Maastricht 6202 AZ
NL
Scientific
Selecteer

Oxfordlaan 10
Maastricht 6202 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Subjects must be candidates for chemotherapy including in the treatment plan platinum-based drugs or taxanes at doses expected to be potentially neurotoxic
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 have a Karnofsky performance score greater than or equal to 70.

Exclusion criteria

1. Poor prognosis, with high probability to be unable to complete the planned chemotherapy treatment.
2. Concomitant neurologic conditions, e.g., brain tumor, spinal or brain metastases.
3. Severe depression that in the opinion of the Investigator would complicate the assessments.
4. Chronic treatment with antiepileptic drugs, antidepressants and major analgesics, unless stable dosing and conditions have been reached for 3 months prior to entry.
5. Subjects with a known presence of peripheral nerve damage due to another illness or medication.
6. Subjects who are currently receiving another medication that has known potential to produce neurologic peripheral nerve toxicity (e.g. metrodiazole or isoniazid).

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):	04-05-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	28-10-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	18-04-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC 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	NL53819.068.15

Study results

Date completed: 12-01-2017

Actual enrolment: 5

Summary results
Trial is onging in other countries