Probing the role of sodium channels in painful neuropathies (PROPANE Study)

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To investigate whether sodium and potassium mutations are found in a cohort of patients with small fiber neuropathy, painful diabetic neuropathy (versus diabetes patients with no or only minor symptoms) and in patients with breast, ovarium or...

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

Summary

ID

NL-OMON43862

Source
ToetsingOnline

Brief title
PROPANE Study

Condition

- Peripheral neuropathies

Synonym
painful neuropathy, Peripheral neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Europese Unie

Intervention

Keyword: - Nav 1.7, - painful peripheral neuropathy, - voltage-gated ion channels

Outcome measures

Primary outcome

The presence of mutations in SCN3A, SCN6A, SCN9a, SCN10a, SCN11a genes, in addition, in those patients with small fiber neuropathy or idiopathic neuropathy without mutations in the sodium channels and high chance of a genetic origin (age at onset < 40 years and/or positive family history) whole exome sequencing will be performed.

Secondary outcome

na.

Study description

Background summary

Worldwide there is an increase in incidence and prevalence of patients suffering from peripheral neuropathies. This is mainly attributed to the aging process, increasing population of patients suffering from diabetes mellitus and also the long-term neurotoxic effect of various medications including chemotherapeutic agents. Despite the various pathophysiological mechanisms addressed, many questions are still unanswered and most patients are left with numerous complaints and do not receive proper therapy. Painful peripheral neuropathy is perhaps the most excruciating form of peripheral neuropathy. Recently, genetic studies have linked ion channels, particularly its sodium and potassium forms, to the pain pathophysiology and these channels are perhaps potential targets for future treatment of chronic pain.

Study objective

To investigate whether sodium and potassium mutations are found in a cohort of patients with small fiber neuropathy, painful diabetic neuropathy (versus diabetes patients with no or only minor symptoms) and in patients with breast, ovarium or prostate cancer that have developed painful Taxane induced

peripheral neuropathy or patients with coloncancer and with oxaliplatin induced peripheral neuropathy (versus a group of breast cancer patients that did not develop any pain or only experienced minor symptoms after Taxane or oxaliplatin therapy).

Study design

patients will be recruited in close collaboration with oncologists and endocrinologists based at the Spaarne hospital, Hoofddorp, Maastricht University Medical Centre, Maastricht, in the Netherlands and at the *Carlo Besta* Neurological Institute, Milan, Italy. Patients will be profiled at these three hospital and genetic studies will be conducted at Maastricht University Medical Centre, Maastricht, the Netherlands

Study burden and risks

Patients will complete several questionnaires (estimated time 30 minutes)(addendum), and will undergo QST and skinbiopsy. QST is a noninvasive, painless test of temperature sensation. Durations of QST is 30 minutes. Skin biopsy for determination of IENF density is a minimal invasive procedure. Estimated time ~10 minutes. There is a very small risk of getting an infection. Some people get a scar at the site of the biopsy (often less than 3mm, conform the size of the punch biopsy). NCS is part of care as usual for patients with polyneuropathy.

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

Subjects with Painful PN must meet all of the following inclusion criteria to be eligible for participation:
a. Fulfillment of the international diagnostic criteria for snall fiber neuropathy, for painful diabetic neuropathy or for chemotherapy induced PN by taxane in breast, ovarian or prostate cancer and oxaliplatin in colon cancer. Patients with CIPN have completed their chemotherapy treatment.
b. Maximal pain VAS scores must be at least 40 (range: 0 - 100) (without neuropathic pain medication; in case of use of neuropathic pain medication, the VAS-score in the past without medication to the best of patients knowledge will be used)
c. Age 18 years or older.
d. Each subject will receive an information leaflet and an informed consent form. Subjects must give informed consent by signing and dating an informed consent form prior to study entry. Subjects must be willing to complete all study-related activities and examination required by the protocol.
e. For the control groups, maximal pain VAS scores must be less than 40, preferably < 25 (range: 0 - 100).;Healthy controls (n = 20) must meet the following inclusion criteria to be eligible for participation:
a. Age of 30 - 80 years
b. Absence of the diagnosis of neuropathy or chronic pain disorders

Exclusion criteria

Concomitant diseases that might interfere with the interpretations of the results.

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):	01-03-2012
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	10-06-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-12-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-08-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-12-2014
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-10-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-04-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-06-2016
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	NL36128.068.11