Neuropathic Pain: development and validation of a clinical prediction rule

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Primary: to develop and validate a clinical prediction rule to predict a favourable or unfavourable disease course for NP patients, therewith enabling tailor made treatments for NP patients.Secondary: determine prevalence of clinical signs of NP in…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON41339

Source
ToetsingOnline

Brief title
Prediction of Neuropathic Pain

Condition

- Other condition
- Peripheral neuropathies

Synonym
'nerve pain', 'neuropathic pain'

Health condition

laesie of ziekte van het somatosensorische systeem, aandoening van het centrale of perifere zenuwstelsel

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Pfizer,Pfizer bv

Intervention

Keyword: Neuropathic Pain, Prediction

Outcome measures

Primary outcome

Primary study parameters:

severeness of pain, measured using the Numeric Rating Scale (NRS)

severeness of neuropathic pain, measured using the Neuropathic Pain Scale (NPS)

Secondary outcome

Secondary study parameters:

Signs of NP (hyper/hypoalgesia, deep pressure pain, hyper/hypoesthesia,

allodynia, vibration sense, joint position sense, two point discrimination),

measured using bedside-QST

Signs of sensory dysregulation, measured using diffuse noxious inhibitory

control (DNIC) and summation

Patient Global Impression of Change (PGIC)

Self Efficacy Scale

Disability Rating Index (DRI)

Impact on Participation and Autonomy (IPA)

Quality of Life, measured using SF-36 and Euroqol

Physical co-morbidity, measured using Cumulative Illness Rating Scale-Geriatric

(CIRS-G)

Depression / Trait anxiety, measured using Hospital Anxiety Depression Scales

(HADS)

Pain coping, measured using Pain Coping Inventory (PCI)

Catastrophizing, measured using Pain Catastrophizing Scale (PCS)

Fear of movement, measured using Tampa Scale for Kinesiophobia (TSK)

Age

Gender

Education

Treatment

Medical consumption

Work status

Social support

Study description

Background summary

Neuropathic Pain is a disorder that is difficult to define. Consequently, described incidence rates vary and patient populations are heterogenous. Because of this, getting uniformity on the prognosis and best medical treatment of this disease is difficult. However, it is generally accepted that NP forms a substantial problem in patient care, and consequences for the patients quality of life, daily functioning and participation are severe.
Early evaluation of prognostic factors and uniformity in diagnosis and treatment for patients with NP are necessary to improve medical care for these patients. Development of a clinical prediction rule for NP may contribute to identification of patients at risk for chronification, and enable tailor made treatments for NP patients, therewith reduce patient and societal burden associated with this disease.

Study objective

Primary: to develop and validate a clinical prediction rule to predict a

favourable or unfavourable disease course for NP patients, therewith enabling tailor made treatments for NP patients.

Secondary: determine prevalence of clinical signs of NP in a general population of pain patients of regional medical care centers; determine the relationship between pain related variables at different levels of observation for NP (cross-sectional and longitudinal).

Tertiary: implementation of the bedside-QST and the prediction rule that has been developed to other treatments (mono- and multidisciplinary).

Study design

Longitudinal observational research in three hospitals. One cohort will be used for the development of the prediction rule (VUMC), two cohorts will be used to validate the prediction rule (UMCM and OLVG).

Patients will be asked to fill in questionnaires and to undergo simple non-invasive measurements. Measurements will be performed at inclusion and after 3, 6 and 12 months. Predictive models will be made for 3 and 6 months. The best working model (concerning prediction and validity) will be implemented. The 12-months measurement will be used to assess the long term disease course for these NP patients.

Validated measurement instruments, applicable for the Dutch language, will be used. Measurement values will be collected in a CRF or a diary.
Physical measurements / examinations are non-invasive. Signs of NP will be measured according to the bedsite-QST with the Semmes Weinstein Monofilaments test, the pressure algometer, the modified INCAT sensory scale (pinprick, vibration, light touch, joint position sense). DNIC and summation will be used to measure signs of sensory dysregulation. Measurements will be performed at the most affected area of the most affected bodypart.

Study burden and risks

Burden on the patients:
4x 1 hour filling out questionnaires
4x 1 hour non-invasive simple physical tests at the VUmc

Risk associated with participation: none

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

A for neuropathic pain plausible anatomical distribution of the pain and/or a clinical record that indicates a lesion or disease of the central or peripheral nervous system.;At least 2 positive signs from a bedsite-QST-protocol;Able to speak Dutch adequately;Signed informed consent

Exclusion criteria

terminally ill patients
patients who don't speak Dutch adequately
no informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2010
Enrollment:	480
Type:	Actual

Ethics review

Approved WMO Date:	07-01-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-04-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2015
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	NL30114.029.09