PainDETECT-Questionnaire and DN4: A Dutch validation study in patients with low back pain, neck shoulder pain or with a neuropathic pain syndrome

Published: 23-02-2009
Last updated: 06-05-2024

Objective: The aim of this study is to validate the Dutch versions of the PainDETECT questionnaire PD-Q and the *Douleur neuropathique en 4 questions* (DN4) for use in primary and specialist medical care settings for patients with LBP and NSP and…

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

Summary

ID

NL-OMON33911

Source
ToetsingOnline

Brief title
Validation of the PDQ & DN4

Condition

- Peripheral neuropathies

Synonym
Nerve pain; Neuropathic pain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Farmaceutische industrie;Pfizer bv (Project DALI voor PIJN),Pfizer

Intervention

Keyword: Neuropathic pain, Questionnaires, Translation, Validation

Outcome measures

Primary outcome

1. Outcome of the gold standard: The clinical examination serves as the goldstandard. Based on the grading system of Treede et al (2008), The gold standard is based on a standardized assessment performed by two independant working physicians. 2. Outcome of PDQ & DN4. 3. Outcome of Quantitative Sensory testing (QST): The German Research Network for Neuropathic Pain QST (GRNNP QST) protocol will be used (Rolke et al. 2006;Rolke et al. 2006).

Secondary outcome

1. Medical comorbidity: Questionnaire with the most prevalent and relevant medical 2. Mental health status: Hospital Anxiety Depression Scale (HADS) (Spinhoven et al. 1997). 3. Functioning: Disability Rating Index (DRI) (Salen et al. 1994). 4. Health related quality of life: Short form-36 (SF-36). 5. Pain Attribution Scale(Kraaimaat 200?). 6. prevalence of neuropathic pain in this patient groups.

Study description

Background summary

Neuropatic pain plays an important role in the chronification of low back pain (LBP) and neck and shoulder pain (NSP) which are both highly prevalent and clinically important medical and societal problems. However, in clinical

practice it is often difficult to diagnose the neuropathic pain component in (sub)acute and chronic pain of the low back and neck shoulder region. It is considered helpful to have a screening tool to identify neuropathic pain in individual patients. Beside an optimal sensitivity and specificity this screening tool should be short and easy to apply to use in clinical practice, not only in the first visit but also during follow up. At this moment, such an instrument is not available in the Netherlands. Besides an optimal sensitivity and specificity the instrument should be easy to fill in during first visit and follow-up. The PainDETECT-Questionnaire(PD-Q) (Freynhagen et al. 2006) and the Douleur Neuropatique en 4 questions (DN4) (Bouhassira et al. 2005) are developped in respectively Germany and France. These questionnaires have a high sensitivity and specificity and predictive value. The PDQ and DN4 are recently translated to the Dutch language, but not validated in patients with LBP, NSP and neuropathic pain syndromes (NPS).

Study objective

Objective: The aim of this study is to validate the Dutch versions of the PainDETECT questionnaire PD-Q and the *Douleur neuropathique en 4 questions* (DN4) for use in primary and specialist medical care settings for patients with LBP and NSP and patients with neuropathic pain syndromes (NPS). The second objective is to assess the prevalence of neuropathy in patients with LBP and NSP in the Netherlands. Furthermore, this study aims to assess the general health status, mental health status, functioning, pain attribution and quality of life of patients with LBP, NSP and NPS.

Study design

Study design: Cross-sectional research design to study the psychometric quality of the PD-Q and the DN4 with 2 weeks follow-up for test-retest reliability and 3 months follow-up for monitoring and prognosis.

Study burden and risks

Patients have to undergo sensory testing by their physician according to good clinical practice. When this is finished, another physician will perform the examination of the patient again. The patient have to fill in 6 supplementary questionnaires (30 minutes) afterwards. When both physicians have consensus about the diagnosis, the patient will eventually be asked to undergo the QST measurement (88 patients). The QST measurement is a not invasive sensory measurement protocol to detect the threshold for, warmth, cold, touch, vibration and pain on the patients skin. For QST testing the patient has to make a new appointment en has to visit to the Radboud University Nijmegen Medical Centre (30 minutes). After 2 weeks (test retest reliability) and 3 months (monitoring/prognosis), all patients receive a second PDQ and DN4 by

mail at their home (10 minutes to fill in).

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

Men & Women; at least 18 years old
More than 3 months pain complaints as decripted above
Pain Intensity Score > 3 (NRS)

Exclusion criteria

patients with multiple painsyndromes

Pain with an oncologic cause
severe psychiatric disorder
Abuse of alcohol and drugs
Problems to understand the Dutch language

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-10-2009
Enrollment:	438
Type:	Actual

Ethics review

Approved WMO

Date:	23-02-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL25343.091.08