Validation of the PDQ & DN4.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23306

Source
NTR

Health condition

Neuropathic pain
questionnaires
Translation
Validation

Neuropathische pijn
Vragenlijsten
Vertaling
Validatie

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre
Source(s) of monetary or material Support: This study was performed within DALI for PAIN, a national program that focuses on neuropathic paincare optimalisation. DALI for PAIN is an initiative of Pfizer. This project is supported by an unrestricted grant from Pfizer.

Intervention

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) in 20% of the study population.

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

N/A

Study 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

1. Medical history, standardized gold standard, Questionnaires PDQ, DN4, DRI, HADS. SF-36, PAS + QST in 20% of the study population;

2. 2 weeks follow-up (test-retest reliability): PGIC, PDQ, DN4;

3. 3 months follow-up: PGIC, PDQ, DN4 (sensitivity for change, prognostic value).

Intervention

Cross-sectional research design to study the psychometric quality of the PD-Q and the DN4 as compared to a gold standard (Diagnosis by two independant physiciqans), QST (20% of the study population) and the Grading System by Treede et al. (Neurology, 2008) with 2 weeks follow-up for test-retest reliability and 3 months follow-up for monitoring and prognosis.

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Eligibility criteria

Inclusion criteria

1. Men & Women;

2. At least 18 years old;

3. More than 3 months pain complaints of low back pain, neck shoulder pain radiating into respectively leg(s) or arm(s) or a neuropathic pain syndrome.

Exclusion criteria

1. Patients diagnosed with malignancy, compression fractures, ankylosing spondylitis or fibromyalgia;

2. Patients with painful syndromes of unknown origin or associated with diffuse pains, severe mental illness, chronic alcoholism or substance abuse;

3. Inability to fill in the questionnaire adequately;

4. Not capable to understand the Dutch language.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-02-2009
Enrollment:	438
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-08-2011
Application type:	First submission

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
NTR-new	NL2884
NTR-old	NTR3030
Other	CCMO : ABR 25343/Dossier NL25343.091.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A