Validation of the PDQ & DN4.

Gepubliceerd: 18-08-2011 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23306

Bron
Nationaal Trial Register

Aandoening

Neuropathic pain
questionnaires
Translation
Validation

Neuropathische pijn
Vragenlijsten
Vertaling
Validatie

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre
Overige ondersteuning: 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.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-02-2009
Aantal proefpersonen:	438
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-08-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A