

DN4 mixte - Evaluation study of the DN4 questionnaire in mixed pain

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General

Identification

Detailed name	Evaluation study of the DN4 questionnaire in mixed pain
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Sign or acronym	DN4 mixte
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL N°907211
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General Aspects

Medical area	Neurology
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Others (details)	neuropathic pain
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Keywords	DN4 questionnaire, evaluation
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Scientific investigator(s) (Contact)

Name of the director	Millet
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Surname	Véronique
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Unit	Pfizer
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Organization	Pfizer
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Collaborations

Funding

Funding status	Private
Details	Pfizer
Governance of the database	
Sponsor(s) or organisation(s) responsible	Pfizer
Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Recruitment through participating doctors
Database objective	
Main objective	Main: Compare the average scores of the DN4 questionnaire observed in 4 sub-groups of patients monitored for lumbar radiculalgia. Secondary objectives: - For each item on the DN4, compare the proportion of the positive items between each sub-group. - Compare the proportions of the subjects that have a DN4 score > 4/10 between each sub-group. - Compare the proportions of the subjects that have been considered as having neuropathic component by a 1st investigator between each sub-group. - Estimate the sensitivity, specificity, the positive and negative predictive value of the DN4 scale in relation to the opinion of the 1st investigator within each sub-group: - o By taking a DN4 threshold at 4/10 - o Using the ROC curve

- Compare the averages of the scores of the modified Schöber index and the "hand-to-floor distance" according to the presence or not of a neuropathic component in the 4 sub-groups.

Inclusion criteria

Patients ? 18 years,
- First consultation in an investigating center,
- Patients having a lumbar pain with or without radiculalgia (patients presenting another pain of moderate to severe were excluded),
- Pain present for at least 3 months,
- Moderate to severe pain (intensity ? 4 on the 11-point Lickert scale),
- Patients who have signed the written consent.

Population type

Age
Adulthood (19 to 24 years)
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)
Elderly (65 to 79 years)
Great age (80 years and more)

Population covered Sick population

Gender
Male
Woman

Geography area National

Detail of the geography area Metropolitan France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 2007

Date of last collection (YYYY or MM/YYYY) 2009

Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals 132

Data

Database activity Data collection completed

Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Face to face interview
Presence of a biobank	No
Health parameters studied	Health care consumption and services
Care consumption (detail)	Medical/paramedical consultation
Procedures	
Data collection method	Paper CRF
Participant monitoring	Yes
Details on monitoring of participants	1 to 3 days
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Methods for accessing the database are currently being defined
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only