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
Sign or acronym	DN4 mixte
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL N°907211

General Aspects

Medical area	Neurology
Others (details)	neuropathic pain
Keywords	DN4 questionnaire, evaluation

Scientific investigator(s) (Contact)

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Unit	Pfizer
Organization	Pfizer

Collaborations

Funding

Funding status	Private
Details	Pfizer

Governance of the database

Sponsor(s) or organisation(s) responsible	Pfizer
Organisation status	Private

Additional contact

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 lumber 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