## 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 ${ }^{\circ} 907211$ |
| 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

Pfizer

## Governance of the database

Sponsor(s) or organisation(s) responsible

Organisation status

Pfizer

Private

## Additional contact

Main features
Type of database

Type of database
Study databases (details)
Database recruitment is carried out by an intermediary

Database recruitment is carried No out as part of an interventional study

Additional information regarding sample selection.

Study databases
Longitudinal study (except cohorts)
A selection of health institutions and services

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 subgroup.
- 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, <br> - First consultation in an investigating center, <br> - Patients having a lumber pain with or without radiculalgia (patients presenting another pain of moderate to severe were excluded), <br> - Pain present for at least 3 months, <br> - Moderate to severe pain (intensity ? 4 on the 11point Lickert scale), <br> - Patients who have signed the written consent. |
| Population type |  |
| Age | Adulthood (19 to 24 years) <br> Adulthood (25 to 44 years) <br> Adulthood ( 45 to 64 years) <br> Elderly ( 65 to 79 years) <br> 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

| 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 |

