POSTHER - Burden of herpes zoster and postherpetic neuralgia among people ? 50 years old in France

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General

Identification

Detailed name	Burden of herpes zoster and postherpetic neuralgia among people ? 50 years old in France
Sign or acronym	POSTHER
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	915162

General Aspects

Medical area	Dermatology, venereology Neurology
Pathology (details)	Zona
Health determinants	Others (specify)
Others (details)	viral infection
Keywords	zona, varicella zoster virus, VHZ, vaccination

Scientific investigator(s) (Contact)

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Unit	GSK

Collaborations

Participation in projects, networks and consortia	No

Funding

Funding status	Private
Details	Paid by the Sponsor

Governance of the database

Sponsor(s) or organisation(s) responsible	GlaxoSmithKline
Organisation status	Private
Presence of scientific or steering committees	Yes

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health care professionals
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	An observational, prospective cohort study of patients ? 50 years old with a HZ diagnosis, carried out by a national random sample of community first line practitioners concerned by HZ diagnosis: general practitioners (GPs), dermatologists and ophthalmologists. Inclusion ? HZ cohort: All patients ? 50 years old with a HZ diagnosis (as the primary diagnosis and without history of previous HZ) during approximately 6 months inclusion period will be included in the HZ cohort, until total study target is achieved (competitive inclusion), ? PHN cohort: All patients of the HZ cohort presenting PHN (defined as ZBPI pain ?3) 3 months after HZ rash onset symptoms will be included secondarily in the PHN cohort

Database objective	
Main objective	Research question: To assess the burden of HZ and PHN among people ? 50 years old in France, in terms of healthcare resources used, medical direct and indirect costs, as well as pain severity and impact on quality of life. Primary objective ? To evaluate HZ-related and PHN-related direct medical costs and indirect costs during a 9-month period (overall, by gender and age-classes). Secondary objectives ? To describe HZ and PHN pain severity during a 9-month period (overall, by gender and age-classes), ? To evaluate impact of HZ and PHN on the quality of life of patients during a 9-month period (overall, by gender and age-classes).
Inclusion criteria	Study carried out by a random sample of community first line practitioners concerned by HZ diagnosis: GPs, dermatologists and ophthalmologists. HZ cohort inclusion-exclusion criteria ? Patient with a first visit for a diagnosis of HZ and who attend the clinic within two week of the HZ start of symptoms (defined as unilateral pain accompanied by a unilateral rash without alternative diagnosis), ? Patient ? 50 years old without history of previous HZ, ? Patient who agree to participate and signed informed consent, ? Patient able to understand the study, to complete self-administered questionnaires (alone or with the help of a relative) and to answer to phone interviews. PHN cohort inclusion-exclusion criterion ? Patient of the HZ cohort presenting PHN 3 months after onset of the HZ rash onset (defined as the presence of HZ-associated severe ?worst? pain: pain ? 3 from ZBPI item ?worst pain?)

Population type	
Age	Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Pathology	B02 - Zoster [herpes zoster]

Gender	Male Woman
Geography area	National
Detail of the geography area	France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2016
Date of last collection (YYYY or MM/YYYY)	2016

Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	? 250 cases of HZ and 40 cases of PHN expected

Data

Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Administrative data Cost data Utility / preference data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Phone interview
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Quality of life/perceived health	ZBPI and EQ5D questionnaires

(detail)

Procedures

Data collection method	phone to phone interview, paper self questionnaire
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the participant (mail, e-mail, telephone etc.)
Details on monitoring of participants	follow up by letters, email, phone
Links to administrative sources	No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	to be determined
Access to aggregated data	Access not yet planned
Access to individual data	No access