

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
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Funding

Funding status	Private
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Details	Paid by the Sponsor
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Governance of the database

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

Main features

Type of database

Type of database	Study databases
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Study databases (details)	Cohort study
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Database recruitment is carried out by an intermediary	A selection of health care professionals
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Database recruitment is carried out as part of an interventional study	No
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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 \geq 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 \geq 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 \geq 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