Burden of Herpes Zoster in selected immunocompromised populations in the German Pharmacoepidemiological Research Database (GePaRD)

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Administrative details

PURI

https://redirect.ema.europa.eu/resource/17403

EU PAS number

EUPAS17402

Study ID

17403

DARWIN EU® study

No

Study countries

Germany

Study description

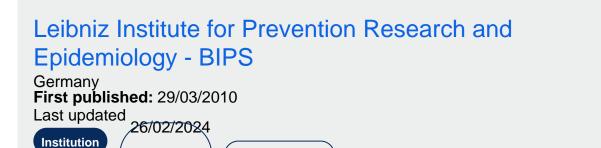
Based on data from statutory health insurance providers, the study investigates the incidence of herpes zoster in patients with different severities of immunosuppression. Besides, frequencies of complications and different aspects of healthcare resource utilisation are examined for herpes zoster patients stratified by severity of immunosuppression.

Finalised

Research institution and networks

Not-for-profit

Institutions



ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Oliver Riedel

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/04/2015 Actual: 01/06/2015

Study start date

Planned: 20/07/2015

Actual: 01/12/2015

Data analysis start date

Planned: 10/08/2015 Actual: 04/01/2016

Date of final study report

Planned: 10/06/2016 Actual: 30/11/2016

Sources of funding

· Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline Biologicals S.A.

Regulatory

Was the study required by a regulatory body? No

Is the study required by a Risk Management Plan (RMP)? Not applicable

Methodological aspects

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary data collection

Main study objective:

To estimate the incidence of herpes zoster and its complications in immunocompromised subjects, aged 18 years and above, overall and stratified by sex, age group, and type of immunocompromising disease or therapy.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Herpes zoster

Population studied

Short description of the study population

Patients aged 18 years and above with different severities of immunosuppression.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Immunocompromised

Estimated number of subjects

1260000

Study design details

Outcomes

Incidence of herpes zoster. Prevalence of herpes zoster complications and frequencies of hospitalisations, physician visits, and treatments with antivirals and analgesics.

Data analysis plan

A cross-sectional design will be used to identify patients with different severities of immunosuppression for the years 2006-2012 based on immunocompromising diseases and drug treatments. A cohort design will be used to calculate annual incidence rates of herpes zoster for the years 2006-2012, stratified by age, sex, and severity of immunosuppression and to analyse the prevalence of herpes zoster complications, physician visits, hospitalisations, and antiviral and analgesic treatments.

Data management

Data sources

Data source(s)

German Pharmacoepidemiological Research Database

Data sources (types)

Administrative data (e.g. claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown