Estimation of Background Incidence Rates of Guillain-Barré Syndrome in Germany in the years 2007-2009 (BIGS)

First published: 14/05/2014
Last updated: 01/04/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/29016

EU PAS number
EUPAS6536

Study ID
29016

DARWIN EU® study
No

Study countries
Germany

Study description
Guillain-Barré syndrome (GBS) is currently the most frequent cause of acute flaccid paralysis worldwide and has been suggested to occur as a severe adverse reaction to several vaccines. An estimation of the age- and sex-specific background incidence rates of GBS constitutes a prerequisite for signal evaluation in the context of vaccine safety monitoring as well as for vaccine safety studies which to date is only insufficiently given in Germany. Referring to a request from the Paul Ehrlich Institute (PEI), which is responsible for the marketing authorization for vaccines in Germany, the main objective of the BIGS-Study was to estimate the background incidence of GBS in Germany in the years 2007-

2009. A focus was set on age- and sex-specific incidence rates as well as on geographic (Western vs. Eastern Germany) and seasonal differences.

Study status
Finalised

Research institution and networks

Institutions

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany
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Last updated
26/02/2024

Institution

ENCePP partner

Not-for-profit

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Tania Schink

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
26/06/2012
Actual:
26/06/2012

Study start date
Planned:
01/01/2006
Actual:
01/01/2006

Data analysis start date
Planned:
01/10/2012
Actual:
15/10/2013

Date of final study report
Planned:
31/03/2013
Actual:
15/04/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi Pasteur MSD

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
EU RMP category 3 (required)

Methodological aspects

Study type

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:
The main objective of this study was to estimate the background incidence of GBS in Germany in the years 2007 to 2009. A focus was set on age- and sex-specific incidence rates as well as on geographic (Western vs. Eastern Germany) and seasonal differences.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medical condition to be studied
Guillain-Barre syndrome

Population studied

Short description of the study population
Residents of Germany.

Age groups
Preterm newborn infants (0 – 27 days)
Term newborn infants (0 – 27 days)
Infants and toddlers (28 days – 23 months)
Children (2 to < 12 years)
Adolescents (12 to < 18 years)
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)

Estimated number of subjects
13297678

Study design details

Outcomes
The primary outcome of this study was the occurrence of GBS, defined by inpatient ICD-10-GM codes, In subanalyses different case definitions were applied (e.g. additional consideration of diagnostic procedures).

Data analysis plan
A retrospective cohort design was applied to estimate the incidence of GBS in the study population for the years 2007-2009. A case of GBS was considered as incident if a GBS diagnosis-free period of at least 12 months preceded a GBS diagnosis. For the main analysis cases were defined by the ICD-10-GM code G61.0 if this was coded as the main discharge diagnosis in inpatient data. In sub- and sensitivity analyses different case definitions were applied in order to assess the effect of the specificity of case definitions on potential variations in incidence estimates. Crude as well as standardized incidence rates per 100,000 person years were calculated for the entire study period and for each study year. Results were stratified by sex, age group, region and season.

Documents

Study publications
Hense S, Schink T, Kreisel SH, Marcelon L, Simondon F, Tahden M, Garbe E. Estim…

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