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

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 institutions and networks

Institutions

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

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Institution **Not-for-profit** **ENCePP partner**

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 use of data

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

13.297.678

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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

German Pharmacoepidemiological Research Database

Data sources (types)

Administrative healthcare records (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