# 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





## 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



## Contact details

### **Study institution contact**

## Tania Schink gepard@leibniz-bips.de

**Study contact** 

gepard@leibniz-bips.de

## **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**

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

## **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

# Unknown Check completeness Unknown

## **Check stability**

**Check conformance** 

Unknown

## **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

Unknown