Incidence rates of adverse events of special interest: Guillain-Barré syndrome and Bell’s palsy

First published: 12/04/2021

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Study Finalised

Administrative details

EU PAS number

EUPAS40527

Study ID

40537

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ United Kingdom

Study description

Background rates of adverse events of special interest (AESIs) are important in order to be able to determine if an event rate in patients with a certain drug exposure is higher than expected in the general, non-exposed population. Such background rates can then serve as comparator data when reports of suspected adverse reactions are reviewed, for example in the case of immune-mediated or neurologic events for COVID-19 vaccines. This study assesses the feasibility of generating background rates of events of interest in the IMS® Disease Analyzer databases, using two AESIs as a case study: Guillain-Barré syndrome (GBS) and Bell's palsy. The present study has obtained event rates for Guillain-Barré syndrome and Bell's palsy using similar methods as in the ACCESS protocol (EUPAS study 37274) 1, 2. Results from this study will be compared to results from ACCESS and from the ADVANCE project 3, 4, which published incidence rates of autoimmune diseases in European healthcare databases 4 between 2003 and 2014. This study also serves as a pilot to define a process for rapid generation of background rates should data be promptly required to address potential safety concerns emerging from the COVID-19 vaccination campaigns.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Karin and Robert Hedenmalm and Flynn

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/01/2021

Actual: 05/01/2021

Study start date

Planned: 05/01/2021

Actual: 05/01/2021

Date of final study report

Planned: 18/03/2021

Actual: 18/03/2021

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

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:

1. To obtain yearly incidence rates for Guillain-Barré syndrome and Bell’s palsy between 2017 and 2019 as pre-COVID-19 event rates in IRMS UK and IMS FR/DE, 2. To stratify the incidence rates for Guillain-Barré syndrome and Bell’s palsy between 2017 and 2019 in the UK, FR and DE by year, gender and age group.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Guillain-Barre syndrome

Bell's palsy

Population studied

Short description of the study population

The study population consisted of patients registered with GPs in the UK who contributed to the IMRD UK databases from 2017 to 2019, who had at least 365 days of observation prior to start of the yearly period and were observable during at least one of day of 2017, 2018 or 2019.

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

100000

Study design details

Data analysis plan

The incidence rate is the calculated as the number of events divided by the total follow up time.

Documents

Study results

IMRD-UK incidence rates Bells palsy and GBS 20210317.pdf(372.61 KB)

Study, other information

IMS FR and DE - incidence rates Bells palsy and GBS.pdf(167.42 KB)

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data source(s), other

THIN

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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

No