

Guillain-Barré syndrome and influenza vaccines: a meta-analysis

First published: 23/01/2015

Last updated: 02/04/2024

Study

Planned

Administrative details

EU PAS number

EUPAS8429

Study ID

8430

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Cases of Guillain-Barré syndrome (GBS) have been occasionally associated with influenza vaccines, this possible risk, even if rare, is a matter of much concern. To learn the strength of this association, a systematic review and a meta-

analysis will be conducted. Controlled observational studies addressing the risk of GBS associated with different influenza vaccines will be sought and eventually included.

Study status

Planned

Research institutions and networks

Institutions

Universidad de Valladolid

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Alfonso Carvajal

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/01/2013

Study start date

Planned: 15/05/2013

Date of final study report

Planned: 03/02/2015

Sources of funding

- Other

More details on funding

Universidad de Valladolid

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The specific aim of this study was to explore the possible association between influenza vaccines and Guillain-Barré syndrome.

Study Design

Non-interventional study design

Systematic review and meta-analysis

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

ANTIGENS OF THE INFLUENZA VIRUS A/CALIFORNIA/7/2009 (H1N1)-LIKE VIRUS
PDM09

Medical condition to be studied

Guillain-Barre syndrome

Population studied

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)

Estimated number of subjects

99999999

Study design details

Data analysis plan

Overall risk estimation (RevMan / Cochrane)

Data management

Data sources

Data sources (types)

[Published literature](#)

[Other](#)

Data sources (types), other

Meta-analysis: Pub Med and EMBASE

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