A post-marketing active surveillance study to evaluate the risk of Guillain-Barré syndrome, acute disseminated encephalomyelitis, and atrial fibrillation in adults 50 years and older vaccinated with GSK’s Arexvy vaccine in the United States (220149)

First published: 06/03/2025

Last updated: 05/09/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000486

Study ID

1000000486

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions and networks

Institutions

GlaxoSmithKline Biologicals SA

Harvard Pilgrim Health Care Institute

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

CVS Health, Carelon Research, HealthPartners, Humana, Point32Health

Contact details

Study institution contact

Call Center EU GSK Clinical Trials RD.CTT-globalmailbox@gsk.com

Study contact

RD.CTT-globalmailbox@gsk.com

Primary lead investigator

Call Center EU GSK Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/05/2023

Actual: 22/05/2023

Study start date

Planned: 15/03/2025

Actual: 14/03/2025

Date of final study report

Planned: 31/10/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline Biologicals SA

Study protocol

Protocol Amendment 2 Anonymised 24 Jan 2025.pdf (1.5 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Non-interventional study

Main study objective:

To evaluate whether Arexvy vaccine is associated with an increased risk of new-onset Guillain-Barré syndrome (GBS) and new-onset acute disseminated encephalomyelitis (ADEM), within specified time periods after vaccination among people ≥50 years of age.

Study Design

Non-interventional study design

Case-only

Study drug and medical condition

Medicinal product name

AREXVY

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

RESPIRATORY SYNCYTIAL VIRUS, GLYCOPROTEIN F, RECOMBINANT, STABILISED IN THE PRE-FUSION CONFORMATION, ADJUVANTED WITH AS01E

Medical condition to be studied

Atrial fibrillation

Guillain-Barre syndrome

Encephalomyelitis

Additional medical condition(s)

New-onset Guillain-Barré syndrome; New-onset Acute Disseminated Encephalomyelitis ; New-onset Atrial fibrillation

Population studied

Short description of the study population

Health plan members ≥50 years of age are included in study if they: 1) received one dose of Arexvy; 2) had 365 days of continuous medical and pharmacy enrolment prior to Arexvy vaccine receipt; 3) had continuous enrolment through the end of the follow-up period; 4) had no evidence of a second dose of Arexvy vaccine during the follow-up period; and 5) had no evidence of another medical product indicated for RSV disease prevention prior to receipt of Arexvy vaccine or during the follow-up period.

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

4400000

Study design details

Setting

Health plan administrative claims data held by 5 Research partners who are participating in the US FDA’s Sentinel System.

Outcomes

New-onset GBS in adults ≥50 years of age in the US using claims;
New-onset ADEM in adults ≥50 years of age in the US using claims;
New-onset AF (atrial fibrillation) in adults ≥50 years of age in the US using claims.

Data analysis plan

Demographic and clinical characteristics of the study (vaccinated) and analytic (vaccinated with outcomes in risk or control periods) cohorts will be described. SCRI-based analyses will use conditional Poisson regression models.

Summary results

A result summary report will be completed at the end of the study.

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), other

US FDA Sentinel System (CVS Health, Carelon Research, HealthPartners, Humana, Point32Health)

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

Sentinel

CDM website

https://www.sentinelinitiative.org/methods-Data-tools/sentinel-common-Data-model

CDM version

8.2.0

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes