A Postmarketing Observational Evaluation of the Safety of FLUENZ in Children and Adolescents With High-risk Conditions

First published: 12/04/2017

Last updated: 17/09/2025

Study Finalised

Administrative details

EU PAS number

EUPAS18527

Study ID

18619

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This was a post-marketing, observational, prospective cohort study. LAIV recipients were identified from records made available by the Clinical Practice Research Datalink (CPRD), which maintains a large database of anonymised longitudinal medical records from primary care in the UK. These records were then linked to the Hospital Episode Statistics (HES) database.Incidence rates of all-cause hospitalisations were monitored through 42 days and 6 months following LAIV administration and compared with rates observed among inactivated influenza vaccine (IIV) recipients and unvaccinated controls, matched by high-risk condition, age, healthcare utilisation and region. Incidence rates of hospitalisation for lower respiratory events (LRE) were also analysed.

Study status

Finalised

Research institutions and networks

Institutions

MedImmune

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Institution

Contact details

Study institution contact

Herve Caspard ClinicalTrialTransparency@astrazeneca.com

Study contact

ClinicalTrialTransparency@astrazeneca.com

Primary lead investigator

Herve Caspard

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/05/2012

Study start date

Actual: 17/09/2013

Data analysis start date

Actual: 01/01/2015

Date of final study report

Actual: 16/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MedImmune

Study protocol

MI-MA194 Protocol_ENCePP.pdf (365.95 KB)

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)

Other study registration identification numbers and links

D2660C00001

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

to assess the safety of FLUENZ in regard to rates of serious adverse events (SAEs) relative to matched trivalent inactivated influenza vaccine (TIV) recipients, matched unvaccinated comparison groups, and within cohort (a self-controlled analysis) among children 2 to 17 years of age who have high-risk underlying medical conditions.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective cohort

Study drug and medical condition

Medicinal product name

FLUENZ

Medical condition to be studied

Asthma

Diabetes mellitus

Cystic fibrosis

Population studied

Short description of the study population

Children 2 to 17 years of age who have high-risk underlying medical conditions.
Following Patients were included:
1. Age 2 through 17 years (prior to 18th birthday) of age at date of vaccination or index date
2. Evidence of a diagnosis of at least one of the following high-risk underlying medical conditions:
Asthma, Cystic fibrosis, Congenital lung abnormalities, Heart disease (significant congenital, valvular, and/or rheumatic heart disease), Renal disease (glomerulonephritis, chronic or congenital kidney disease), Sickle cell anemia, White blood cell disorders, Immunosuppressive disorders (excluding malignancy), Malignancy, Diabetes mellitus, Lipid metabolism disorders, Cerebral palsy, Down syndrome, Any medical condition being treated with chronic aspirin therapy, Pregnancy

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Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)

Special population of interest

Hepatic impaired

Immunocompromised

Renal impaired

Estimated number of subjects

10.000

Study design details

Outcomes

Rate of serious adverse events, rates of lower respiratory serious adverse events and other incident medically attended events of interest among FLUENZ recipients relative to comparison groups

Data analysis plan

Incidence rates were reported as number of subjects with an incident event per 1,000 person-years. If a subject had more than one event in the time period, only the incident event was counted and the child censored afterwards.When comparing LAIV recipients with matched IIV recipients or unvaccinated controls, relative risks, and corresponding 95% confidence intervals (CI) were estimated using conditional Cox proportional hazards models. A period effect defined as a time-varying covariate was added to the model for within-cohort analyses.

Documents

Study results

MI-MA194 Final CSR ENCePP.pdf (483.81 KB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Hospital Episodes Statistics database

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