Post-licensure observational safety study of specific outcomes after Optaflu vaccination among adults in The Health Improvement Network (THIN) database of routine UK primary care records (V58_30OB (FLUPASS1))

First published: 04/07/2013

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS4101

Study ID

23738

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A post authorization safety study of cTIV influenza vaccination in adults in the UK. The objective of the study is hypothesis generating with regard to pre-specified outcomes considered to be biologically plausible adverse events to vaccinations.The outcomes are anaphylactic reactions and angioedema, Bell’s palsy, convulsions, demyelination including Guillain-Barre syndrome (GBS), neuritis, non-infectious encephalitis and vasculitis. Information on exposure, outcomes, demographic details and prevalent medical conditions will be identified from the THIN UK database of primary care records and through follow-up with the primary care practices which contribute to this resource. People exposed to cTIV will be identified and their records searched to identify possible cases of the study outcomes from three months before to six months after the vaccination date. Records for these patients will be reviewed and judged as a case or not by an Adjudication Committee using pre-defined case definitions. The distribution of cases of each study outcome in relation to the vaccination date will be reviewed. When an outcome occurs in a predefined risk window, the ratio of observed (in the risk window) to expected (outside this window) cases will be estimated. The six month incidence rates will also be calculated in total and for those chronic disease groups who are recommended to have influenza vaccinations.

Study status

Finalised

Research institutions and networks

Institutions

Gillian Hall

United Kingdom

First published: 01/04/2022

Last updated: 05/04/2022

Institution | Other | ENCePP partner

Contact details

Study institution contact

Gillian Hall gillian.hall@gchall.com

Study contact

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Primary lead investigator

Gillian Hall

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/03/2013

Actual: 25/03/2013

Study start date

Planned: 16/07/2013

Actual: 20/08/2013

Data analysis start date
Planned: 17/03/2014

Actual: 26/03/2014

Date of interim report, if expected
Planned: 28/04/2014

Actual: 22/04/2014

Date of final study report
Planned: 30/05/2017

Actual: 29/06/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis, now Seqirus

Study protocol

V58_30OB_Revised Protocol_v2_04 APR 13.pdf (644.28 KB)

V58_30OB__Revised_Protocol_V_3_29AUG14 doc_Signed Pdf pdf -encepp.pdf (671.76 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)

Methodological aspects

Study type

Study type list

Study topic:

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 investigate the safety of cTIV vaccination in adults in routine clinical care in the UK with regard to pre-specified outcomes.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observed-to-expected analysis and estimation of incidence in an exposed population.

Study drug and medical condition

Medicinal product name, other

Cell culture trivalent influenza vaccine (Optaflu)

Population studied

Short description of the study population

All permanently registered patients 18 years of age and over with a record on THIN that they have received at least one dose of cTIV vaccine as a seasonal influenza vaccination between September 2012 and March 2014 inclusive.

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

9.000

Study design details

Outcomes

Anaphylactic reactions and angioedema, Bell’s palsy, convulsions, demyelination including GBS, neuritis (optic and brachial), non-infectious encephalitis, thrombocytopenia, vasculitis, paraesthesia and inflammatory bowel disease will be studied

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Data analysis plan

Study outcomes will be identified from three months before vaccination until six months afterwards. Temporal plots will be prepared which show the distribution of each study outcome in relation to the vaccination date in pre-defined risk-windows. These risk-windows will be based on the biologically plausible time frame when an outcome caused by the vaccine might be expected to occur. If an outcome occurs in the risk window, the ratio of observed to expected cases will be calculated to investigate if a signal of an association between cTIV exposure and a study outcome has been generated. The observed rates will be those in the risk window and the expected will be from outside this period. The incidence of each study outcome in the six months after vaccination, in age and sex categories will also be calculated.

Documents

Study results

V58_30OB_Observational Study Report_abstract ENCePP.pdf (36.17 KB)

V58_30OB_Observational_Study_Report_Final_version_1_29Jun16_Signed Pdf.pdf (4.06 MB)

Study publications

Hall GC, Davies PT, Karim MY, Haag MD, O'Leary C. Observational safety study of…

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)

THIN® (The Health Improvement Network®)

Data source(s), other

THIN

Data sources (types)

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

Unknown