202055 - European Medicines Agency (EMA) post-authorisation safety study of influenza vaccine

First published: 14/09/2015

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Study Finalised

Administrative details

EU PAS number

EUPAS10632

Study ID

31683

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The purpose of this study is to conduct a pilot study to explore the potential use of routinely collected data in General Practitioner (GP) practices to conduct enhanced safety surveillance of seasonal influenza vaccines in the UK, as recommended in the EMA interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU. Data routinely collected as part of clinical consultations in primary care will be extracted from nine General Practitioner (GP) practices in order to estimate medically attended Adverse Events of Interest (AEIs), for people who have received an influenza vaccine. This study will also actively follow patients who were exposed to seasonal influenza vaccination for 7 days in three of the nine GP practices using a customised card-based adverse drug reaction reporting system, in order to determine whether a more active approach to surveillance can capture higher rates of AEIs.

Study status

Finalised

Research institutions and networks

Institutions

University of Surrey

Department of Health Care Management and Policy, University of Surrey, UK

Contact details

Study institution contact

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Study contact

Vx.publicdisclosureglobal@gsk.com

Primary lead investigator

Simon de Lusignan

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 27/03/2015

Study start date

Actual: 03/10/2015

Date of final study report

Actual: 16/02/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK Biologicals

Study protocol

gsk-202055-protocol-redact.pdf (273.54 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Other

If ‘other’, further details on the scope of the study

Pilot study to explore the use of routinely collected data in GP practices in the UK to provide timely and relevant information on influenza vaccine safety.

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To conduct a pilot assessing adverse event of interest (AEI) frequencies among flu-vaccinated subjects using routinely collected data in nine primary care practices. Although primary surveillance is of 7-day AEI, events recorded outside this window will not be excluded but will be analysed separately. Three practices will take part in the active surveillance sub-study.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive safety surveillance study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BB01) influenza, inactivated, whole virus

influenza, inactivated, whole virus

(J07BB02) influenza, inactivated, split virus or surface antigen

influenza, inactivated, split virus or surface antigen

(J07BB03) influenza, live attenuated

influenza, live attenuated

Medical condition to be studied

Influenza

Population studied

Short description of the study population

Individuals who receive influenza vaccination in the 9 GP practices between 1 September and 30 November 2015.

Age groups

- 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

11.530

Study design details

Outcomes

o Weekly estimation of vaccine coverage, by age strata, and vaccine brand.o Weekly reporting of AEI rates among subjects vaccinated against seasonal influenza, by age strata, co-morbidity and vaccine brand, from nine GP practices using CMR data and from three GP practices using a card-based adverse event system. Assessment of completeness and timeliness of vaccination data in the CMR, completeness and timeliness of AEI reporting in the CMR and through ADR card reporting (within 14 days of vaccination) and assessment of incidence rates of 5 most frequently reported AEIsreported alongside those available in the literature from a similar population between 1 September 2015 and 30 November 2015.

Data analysis plan

This pilot project will extract routinely collected primary care data from 9 GP practices and an active surveillance approach in 3 of the 9 GP practices to estimate proportions of Adverse events of interest (AEIs) among influenza-vaccinated individuals. Coded data will be extracted and interpreted through the creation of case-definition ontologies, that can be mapped to relevant clinical codes (Read codes). Statistical analysis will consist primarily of reporting rates and proportions. Confidence intervals will be calculated.

Documents

Study results

gsk-202055-clinical-study-report-redact.pdf (4.93 MB)

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 sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, General Practitioner (GP) computerised medical record (CMR) system and card-based adverse drug reaction forms (MHRA Yellow Card)

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