A retrospective observational study on effectiveness of influenza vaccine Supemtek® compared to other vaccines in adults aged 18 years and above in the United Kingdom – a feasibility study

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50746

EU PAS number

EUPAS50220

Study ID

50746

DARWIN EU® study

No

Study countries

United Kingdom

Study status

Ongoing

Research institutions and networks

Institutions

OPEN Health

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Institution

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/02/2022

Study start date
Actual: 01/03/2022

Data analysis start date
Actual: 01/06/2022

Date of final study report
Planned: 31/07/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

The general aim of the study is to gain a better understanding of patients who received influenza vaccine and to evaluate the feasibility to run an effectiveness study of Supemtek® vaccine using UK databases.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

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

influenza, inactivated, split virus or surface antigen

Medical condition to be studied

Influenza

Pneumonia influenzal

Cardiopulmonary failure

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

165331

Study design details

Outcomes

Type and brand of vaccine, Age at flu vaccination, Sex, Ethnicity, Index of multiple deprivation, Smoking status, Weight/BMI, Regions, Charlson Comorbidity Index score, Comorbidities recorded during baseline, Pregnancy status for women at vaccination, Primary care visits (GP) in baseline period, Influenza Vaccination status last 2 years, Pneumonia vaccination status, COVID-19 vaccination status. • Influenza hospitalisations • Pneumonia/influenza hospitalisations • Cardiorespiratory hospitalisations • Death (all cause, cause-specific)

Data analysis plan

The analysis of the primary objectives will be descriptive. Distributions and descriptive statistics of central tendency (medians and arithmetic means) and dispersion (standard deviation, interquartile range) will be presented for quantitative variables wherever possible. Categorical variables will be described with frequencies and percentages. To evaluate differences between groups of patients, Chi-square test will be used for categorical variables Student’s t-tests

or Wilcoxon rank sum tests (if distribution was not normal) for continuous variables. The incidence (and confidence intervals (CI)) of influenza and related hospitalization will be estimated as the number of new diagnoses during the study period dividing by the number of total person-years at risk.

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

Hospital Episode Statistics

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Secondary care 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