Prospective non-interventional cohort study to assess safety and tolerability of Fluval AB 2014/2015 trivalent seasonal influenza vaccine in children, adolescents, adults and elderly subjects (FluvalAB-H-17)

First published: 01/11/2014

Last updated: 15/09/2016

Study Finalised

Administrative details

EU PAS number

EUPAS7842

Study ID

15266

DARWIN EU® study

No

Study countries

☐ Hungary

Study description

The aim of this observational study, is to detect a potential increase in reactogenicity and allergic events that is intrinsic to the product in near real-time as part of the active surveillance of subjects vaccinated with Fluval AB vaccine containing influenza virus strains recommended for the 2014/2015 seasonal epidemics in accordance with the Summary of Product Characteristics. Objective:The objective of the study is to evaluate the occurrence of adverse events (AEs) in vaccinated subjects participating in the study and to rapidly detect any clinically significant change (compared to what was known or expected with the previous vaccine composition) in the frequency and severity of AEIs in vaccinated subjects participating in the study that may indicate a potential for more serious risks as exposure to the vaccine increases.Defined cohorts of children and adults will be actively followed-up seven (7) days after immunisation for AEs following vaccination, with the aim to detect eventual changes (compared to the safety profile defined in the Summary of Product Characteristics) in the frequency and severity of defined AEIs. Six hundred (600) subjects will be vaccinated with Fluval AB vaccine containing influenza virus strains recommended for the 2014/2015 seasonal epidemics in accordance with the Summary of Product Characteristics and participate in the study, evaluated in order to achieve at least five hundred (500) evaluable subjects giving at least one hundred (100) male and female vaccinated subjects in each defined age groups (3-5, 6-12, 13-17, 18-65 years and over 65 years), according to Interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU EMA/PRAC/222346/2014.

Study status

Finalised

Research institutions and networks

Institutions

Országos Epidemiológiai Központ

OEK Ifluenza Laboratórium, H-1097 Budapest, Albert Flórián út 2-6, RE-GULYA Kft., H-1037 Budapest, Erdőalja u. 2, N/A, h-4813 Gyüre, Árpád út 26, Pedia-mix Egészségügyi, Oktatási és Szolgáltató Kft., H-1188 Budapest, Póth Irén u. 80, Mother and Son Bt., H-1097 Budapest, Albert Flórián út 5-7. 1. ép.– B old, ELITANCE Bt., H-1188 Budapest, Póth Irén u. 80, N/A, H-1184 Budapest, Dolgozó u. 12, N/A, H-2339 Majosháza, Árpád u. 30, Bonyhády Egészségügyi Kft., H-2133 Sződliget, Orgona u. 11, MOMED Bt., H-2093 Budajenő, József A. u. 2

Contact details

Study institution contact

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Study contact

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Primary lead investigator

István Jankovics

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/10/2014

Study start date

Planned: 01/12/2014

Actual: 09/12/2014

Data analysis start date

Planned: 08/12/2014

Actual: 16/12/2014

Date of interim report, if expected

Planned: 01/01/2015

Actual: 09/01/2015

Date of final study report

Planned: 01/05/2015

Actual: 27/05/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Fluart Innovative Vaccines Ltd

Study protocol

FluvalAB-H-17 Vizsgálati terv_20141029.pdf(1.33 MB)

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

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

To estimate the occurrence of adverse events in vaccinated subjects participating in the study and to rapidly detect a clinically significant change (compared to what was known or expected with the previous vaccine composition) in the frequency and severity of AEIs in vaccinated subjects participating in the study that may indicate a potential for more serious risks as exposure.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Intensive monitoring schemes, Active surveillance

Study drug and medical condition

Name of medicine, other

Fluval AB suspension for injection

Population studied

Short description of the study population

Children and adults previously vaccinated with a single dose of Fluval AB suspension for injection (influenza vaccine, whole virion, inactivated, adjuvanted).

Age groups

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

600

Study design details

Data analysis plan

All AEs will be coded using the latest approved version of MedDRA. The occurrence rates of AEs will be stratified per age groups and gender, summarized by System Organ Class (SOC), High Level Term (HLT) and Preferred Term (PT), and compared to that expected for Fluval AB vaccine (according to

the SmPC), in order to evaluate the potential for an increased risk related to vaccination therewith, than already known.

Data management

Data sources

Data sources (types)

Disease registry

Drug registry

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