Prospective non-interventional cohort study to assess safety and tolerability of 3Fluart 2017/2018 trivalent seasonal influenza vaccine in children, adolescents, adults and elderly subjects (3Fluart-H-20)

First published: 04/05/2017

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS18936

Study ID

23833

DARWIN EU® study

No

Study countries

Hungary

Study description

The aim of this observational study, which will be initiated right after 3Fluart 2017/2018 seasonal influenza vaccine is licensed and used in a mass vaccination campaign, is to detect a potential increase in reactogenicity and allergic events that is intrinsic to the product in near real-time aiming to mitigate risks before the peak period of seasonal immunisation. The objectives are to evaluate the occurrence of defined Adverse Events of Interests (AEIs) and other 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 compositions in the frequency and severity of Adverse Reactions (ARs) in vaccinated subjects participating in the study. Defined cohorts of children and adults will be actively followed-up seven (7) days after immunisation for AEIs and other AEs following vaccination, with the aim to detect eventual changes in the frequency and severity of related events. Patients will be vaccinated according to the Summary of Product Characteristics (SmPC), in compliance with national vaccination policy decisions in Hungary and standard practice, then, will be involved into the study by signing the patient information and informed consent and forms. Relevant information on AEs will be collected during a follow-up phone contact seven (7) days after vaccination. The duration of the study on a patient basis will be seven (7) days. The study will be conducted in multiple study centres in Hungary. A maximum of six hundred (600) and a minimum of five hundred (500) male and female subjects will be vaccinated with 3Fluart vaccine containing influenza virus strains recommended for the 2017/2018 seasonal epidemics in accordance with the SmPC and involved into the study according to Interim guidence on enhanced safety surveillance for seasonal influenza vaccines in the EU.

Study status

Finalised

Research institutions and networks

Institutions

Gyermek Háziorvosi Rendelő

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Institution

Multiple centres: 11 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Gábor Hacsek

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 03/05/2017

Actual: 03/05/2017

Study start date
Planned: 02/10/2017

Actual: 10/10/2017

Data analysis start date
Planned: 09/10/2017

Actual: 17/10/2017

Date of interim report, if expected
Planned: 02/11/2017

Actual: 06/11/2017

Date of final study report
Planned: 01/06/2018

Actual: 05/04/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Fluart Innovative Vaccines Ltd.

Study protocol

3Fluart-H-20 Vizsgálati terv_v01_20170602.pdf (5.21 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 detect a potential increase in reactogenicity and allergic events that is instrinsic to the product in near real-time as part of the active surveillance of

subjects vaccinated with 3Fluart vaccine containing influenza virus strains recommended for the 2017/2018 seasonal epidemics in accordance with the Summary of Product Characteristics.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Intensive monitoring schemes

Study drug and medical condition

Medicinal product name, other

3Fluart suspension for injection (influenza vaccine, whole virion, inactivated, adjuvanted)

Population studied

Short description of the study population

All subjects vaccinated with a single dose of 3Fluart vaccine containing influenza virus strains recommended for the 2017/2018 seasonal epidemics in accordance with the SmPC will be involved into the study.

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

The assessment of safety and tolerability will be primarily based on the occurrence rates of adverse reactions. The occurrence rates of adverse reactions will be summarized by SOC (System Organ Class) and PT (Preferred Term) and compared to what was already known or expected with 3Fluart vaccine as follows: Evaluation of the occurrence of AEIs and other AEs in vaccinated subjects participating in the study. Occurrence rate of each AE will be presented by age group and severity. Rapid detection of any clinically significant change compared to what was known or expected with the previous vaccine compositions in the frequency and severity of ARs in vaccinated subjects participating in the study. Comparison will be performed between ARs of the study and ARs observed in the last post-authorization safety study performed with 3Fluart influenza vaccine, further, between ARs of the study and with those defined in the SmPC of 3Fluart influenza vaccine.

Documents

Study, other information

3Fluart-H-20 Vizsgálati helyszínek, vizsgálatvezetők felsorolása_v01_20170602.pdf (505.2 KB)

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)

Disease registry

Drug registry

Spontaneous reports of suspected adverse drug reactions

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