Prospective non-interventional cohort study to assess safety and tolerability of 3Fluart 2019/2020 trivalent seasonal influenza vaccine in children, adolescent, adults and elderly subjects (3Fluart-H-27)

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Study | Finalised

Administrative details

EU PAS number

EUPAS29839

Study ID

34741

DARWIN EU® study

No

Study countries

Hungary

Study description

The aim is this observational study, which will be initiated right after 3Fluart 2019/202 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 an 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 consent and forms. Relevant inforamtion 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 2019/2020 seasonal epidemics in accordance with the SmPC and involved into the study according to Interim guidance 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: 10 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: 31/05/2019

Actual: 31/05/2019

Study start date
Planned: 01/10/2019

Actual: 14/10/2019

Data analysis start date
Planned: 08/10/2019

Actual: 21/10/2019

Date of interim report, if expected
Planned: 01/11/2019

Actual: 14/11/2019

Date of final study report
Planned: 01/06/2019

Actual: 20/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Fluart Innovative Vaccines Ltd.

Study protocol

3Fluart-H-27_Vizsgálati terv_v01_20190528.pdf (5.63 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:

Combined primary data collection and secondary use of data

Main study objective:

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 3Fluart vaccine containing influenza virus strains recommended for the 2019/2020 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

The study participant with 3Fluart flu vaccine vaccinated according to the instructions for use persons (both men and women) designed minimal and its maximum number is between the following values: one hundred (100) - one hundred and twenty (120) children aged 3-12, one hundred (100) – one hundred and twenty (120) adolescents aged 13-17, one hundred and fifty (150)

– one hundred and eighty (180) adults aged 18-65, one hundred and fifty (150) - one hundred and eighty (180) over 65 years of age elderly person in order to total minimum five hundred (500), maximum six hundred (600) test subject's evaluable data must be available.
Participation in the investigation is Hungarian and European Union is done in accordance with regulations and practice.

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-27_Vizsgálati helyszínek, vizsgálatvezetők felsorolása_v01_20190528.pdf (530.74 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

No