A Postmarketing Noninterventional Cohort Study of the Safety of Live Attenuated Influenza Vaccine (LAIV) in Subjects 2 Through 17 Years of Age (Flu vaccine feedback study)

First published: 09/10/2014

Last updated: 17/09/2025

Study Finalised

Administrative details

EU PAS number

EUPAS7626

Study ID

15337

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Following the introduction of the interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU, the DSRU is conducting a post authorisation safety (PASS) non-interventional cohort study to determine the incidence of adverse events of interest (AEI) following vaccination with the nasal LAIV, Fluenz Tetra® in the authorised age range (children 2-17 years of age) during the 2014/2015 influenza season. The aim of the study is to rapidly detect a clinically significant change (compared to what was known or expected of the previous year's influenza vaccine) in the frequency and/or severity of expected reactogenicity (local, systemic, or allergic reactions) after administration of nasal LAIV, Fluenz Tetra® in children 2 to 17 years of age that may indicate a potential for more serious risks as the frequency of exposure to the vaccine increases. Vaccinees will be recruited via the mass vaccination programme through GP practices and through the pilot schools vaccination programme. Patient outcomes, validated by GPs where appropriate, will be captured through questionnaires (received via surface mail or the study website) and coded onto the DSRU database. Patients or their guardians will be asked to complete a questionnaire at enrolment and another 14 days after vaccination. Approximately 200 vaccinees consented per age group: (i) 2 years to <5 years (ii) 5 to <11 years (iii) 11 to 17 years, will be recruited although enrolment will continue to ensure the target of a minimum of 100 vaccinees with completed data per age group is reached.

Study status

Finalised

Research institutions and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

Last updated: 16/02/2024

Institution | Not-for-profit | ENCePP partner

Networks

NIHR Medicines for Children Research Network

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Last updated: 01/02/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Saad Shakir

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 28/07/2014

Actual: 28/07/2014

Study start date
Planned: 03/10/2014

Actual: 03/10/2014

Date of final study report
Planned: 27/02/2015

Actual: 18/03/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MedImmune

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

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

Data collection methods:

Primary data collection

Main study objective:

To rapidly detect a clinically significant change (compared to what was known or expected of the previous year’s influenza vaccine) in the frequency and/or severity of expected reactogenicity after administration of Fluenz Tetra® in children 2 to 17 years of age that may indicate a potential for more serious risks as the frequency of exposure to the vaccine increases.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

FLUENZ

Population studied

Short description of the study population

Children 2 to 17 years of age who had received nasal LAIV, Fluenz Tetra® vaccine during the 2014/2015 influenza season.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

600

Study design details

Data analysis plan

Summary descriptive statistics of basic demographic information, patient characteristics, co-morbidities, concomitant medications and AEIs will be presented. Numbers of cases (frequencies) and incidence rates overall, by age group and by batch for each endpoint/recorded adverse event of interest will be included in the expedited summary report.

Data management

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)

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