Passive Enhanced Safety Surveillance (ESS) of Quadrivalent Live Attenuated Influenza Vaccine (QLAIV) Fluenz Tetra in Children and Adolescents during the early 2015/2016 Influenza Season in England

First published: 16/09/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28395

EU PAS number

EUPAS15277

Study ID

28395

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This was a passive enhanced safety surveillance (ESS) project on the live-attenuated nasal influenza vaccine, Fluenz Tetra®. The aim of the surveillance was to rapidly detect changes in the frequency or severity of reactions to the vaccination in children during the 2015/2016 influenza season. The surveillance was conducted to satisfy the European Medicines Agency's (EMA) requirement for enhanced safety surveillance for seasonal influenza vaccines in the EU. Children were provided with a Safety Report Card with an integrated consent form following vaccination for completion by their parents in the event that any suspected side effects were experienced. Any data received was collated and analysed and a report submitted to the EMA.

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

First published: 01/02/2024

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

Actual: 24/07/2015

Study start date

Actual: 01/10/2015

Date of final study report
Actual: 10/03/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

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 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:

Development of early influenza season passive Enhanced Safety Surveillance (ESS) for Fluenz Tetra, in children and adolescents in England, with pilot implementation in the 2015 ‘flu season.

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 and adolescents aged 2–17 years administered with QLAIV (exposure) at participating vaccination sites. Vaccinees with co-morbidities, who take medication, or who received additional vaccines on the same day or within 1 month of receiving QLAIV were included

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

10000

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 study report.

Documents

Study publications

McNaughton R, Lynn E, Osborne V, Coughtrie A, Layton D, Shakir S. Safety of int...

Data management

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

Unknown