Postmarketing Safety Study of Q/LAIV in Subjects 2 Through 49 Years of Age

First published: 11/10/2013

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS4848

Study ID

15446

DARWIN EU® study

No

Study countries

☐ United States

Study description

Children and adults will be immunized with Q/LAIV as part of routine clinical practice at Kaiser Permanente Northern California (NCKP) sites. Using existing data on healthcare utilization, rates of medically attended events (MAEs) of

interest will be evaluated in all eligible Q/LAIV recipients who are vaccinated in the Kaiser Permanente (KP) Northern California Health Care Plan during the 2013-2014 influenza season. Enrollment must include a minimum of 10,000 children 2 through 8 years of age, based on previous utilization of FluMist at NCKP, enrollment is expected to include approximately 80,000 children and adults 2 to 49 years of age.Similar to previous postmarketing safety studies conducted with trivalent LAIV, this study will be conducted using data collected by the KP Vaccine Study Center. Incidence rates of MAEs and hospitalizations during periods at risk after Q/LAIV vaccination will be compared versus incidence rates during reference periods later in the follow-up (within-cohort analysis) and versus rates in 2 nonrandomized control groups: matched unvaccinated controls and matched concurrent inactivated influenza vaccine (IIV) recipient controls identified from the KP healthcare database. Trivalent inactivated vaccine (TIV) recipients will serve as controls along with quadrivalent inactivated influenza vaccine (QIIV) recipients if a QIIV is approved and administered during the study period.

Study status

Finalised

Research institutions and networks

Institutions

Kaiser Permanente Southern California (KPSC)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Roger Baxter

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/10/2013

Actual: 18/10/2013

Study start date

Planned: 18/10/2013

Actual: 18/10/2013

Data analysis start date

Planned: 15/04/2015

Actual: 15/04/2014

Date of interim report, if expected

Planned: 30/11/2014

Actual: 21/11/2014

Date of final study report

Planned: 30/06/2018

Actual: 09/08/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MedImmune

Study protocol

pass-protocol-ma-va-medi3250-1115.pdf (1.82 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

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:

Secondary use of data

Main study objective:

To assess the safety of Q/LAIV vaccination in children and adults 2 through 49 years of age within 180 days after vaccination

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BB03) influenza, live attenuated

influenza, live attenuated

Population studied

Short description of the study population

Individuals aged 2 through 49 years (prior to 50th birthday) at the time of vaccination (or index date for unvaccinated controls) who had membership in the Kaiser Permanente (KP) Health Care Plan for at least 12 months prior to vaccination/index date and continuous enrollment in the KP Health Care Plan through 6 months following vaccination/index date.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

80000

Study design details

Outcomes

Rates of medically attended events from 0 to 3 days: hypersensitivity, seizures/convulsionsRates of medically attended events from 1 to 42 days: lower respiratory tract infection, wheezing, Guillain-Barré syndrome, Bell’s palsy, encephalitis, neuritis, vasculitis, any hospitalization and respiratory hospitalizationsRates of medically attended events from 1 to 180 days: narcolepsy/cataplexy

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Data analysis plan

Incidence rates of adverse events of interest during periods at risk after quadrivalent live attenuated influenza vaccine (Q/LAIV) vaccination will be

compared to incidence rates during reference periods later in the follow-up (within-cohort analysis) and to incidence rates in controls (matched unvaccinated subjects and matched inactivated vaccine recipients).Relative risks (RR) and corresponding 95% confidence intervals (CIs) will be constructed for each event for safety comparisons with control groups. Crude RR and adjusted hazard ratio (HR) and corresponding 95% CIs for each event will be derived.Crude RR and exact 95% CI will be calculated without adjustment of any covariate. Adjusted HR and corresponding 95% CI will be obtained using Cox proportional hazards model with calendar time data input adjusting for seasonal changes in background rates and other confounders.

Documents

Study results

MEDI1115 CSR Synopsis FINAL 02Sept2016.pdf (250.99 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.

Conflicts of interest of investigators

Declaration of Interests - R. Baxter.pdf (686.54 KB)

Signed code of conduct

Annex 3 - Declaration - signed.pdf (233.83 KB)

Signed code of conduct checklist

Annex 2 - Checklist - signed.pdf (1.32 MB)

Signed checklist for study protocols

ENCePP checklist completed and signed.pdf (821.13 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Kaiser Permanente/Northern California clinical databases

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