A Case Control Study of the Effectiveness of Q/LAIV Versus Inactivated Influenza Vaccine and No Vaccine in Subjects 2-17 Years of Age (ICICLE)

First published: 10/09/2015

Last updated: 15/09/2016

Study Ongoing

Administrative details

EU PAS number

EUPAS10954

Study ID

15275

DARWIN EU® study

No

Study countries

- ☐ United Kingdom
- ☐ United States

Study description

This is a post-marketing case-controlled study of the effectiveness of a quadrivalent live attenuated influenza vaccine (Q/LAIV/FluMist® Quadrivalent) versus Inactivated Influenza Vaccine (IIV) and No Vaccine in subjects 2-17 years of age.

Study status

Ongoing

Research institutions and networks

Institutions

MedImmune

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Institution

Contact details

Study institution contact

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Study contact

caspardh@medimmune.com

Primary lead investigator

Herve Caspard

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 02/01/2013

Actual: 02/01/2013

Study start date
Planned: 02/12/2013

Actual: 02/12/2013

Data analysis start date
Planned: 30/04/2014

Actual: 30/04/2014

Date of interim report, if expected
Planned: 30/10/2014

Actual: 30/10/2014

Date of final study report
Planned: 01/11/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MedImmune

Study protocol

protocol-admin-change-1.pdf (90.5 KB)

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

This is a post-marketing case-controlled study of the effectiveness of a quadrivalent live attenuated influenza vaccine (Q/LAIV/FluMist® Quadrivalent) versus Inactivated Influenza Vaccine (IIV) and No Vaccine in subjects 2-17 years of age.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medical condition to be studied

Influenza

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

5200

Study design details

Outcomes

Identification of cases positive for wild-type influenza with an end-point PCR genotyping assay.

Data analysis plan

Vaccine Effectiveness is defined as 100 x (1-odds ratio), where the odds ratio is the odds of exposures (Q/LAIV versus Inactivated Influenza Vaccine or no vaccine) among laboratory confirmed cases of flu versus controls. Effectiveness will be monitored by flu season, class of age and by influenza strain.

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)

Other

Data sources (types), other

Prospective patient-based data collection

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