Pilot study: reactogenicity surveillance in Belgium following immunization with seasonal influenza vaccines

First published: 05/10/2016

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS15696

Study ID

28016

DARWIN EU® study

No

Study countries

☐ Belgium

Study description

Background: The EMA calls for a strategy for enhanced safety surveillance of seasonal influenza vaccines. In order to mitigate risks associated with potential new safety concerns within the first month after the start of immunisation, the strategy aims to detect a potential increase in reactogenicity and allergic events in near real-time in the earliest vaccinated cohort.Objective: In this pilot study, we will assess the feasibility of conducting a rapid assessment of reactogenicity of seasonal influenza vaccines in Belgium. The primary objective is to assess whether the required data can be collected in a timely manner. Methods: We aim to recruit subjects aged 18 to 65 years who will have received inactivated seasonal influenza vaccine through routine clinical practice in occupational setting. For seven days, subjects will receive a daily SMS with a link to a web-based questionnaire where reactogenicity events and their severity will be solicited.

Study status

Finalised

Research institutions and networks

Institutions

P95 Clinical and Epidemiology Services

- ☐ Belgium
- ☐ Colombia
- ☐ Netherlands
- ☐ South Africa
- ☐ Thailand
- ☐ United States

First published: 07/11/2022

Last updated: 21/02/2025

Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Antoon De Schryver

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/09/2016

Actual: 14/09/2016

Study start date

Planned: 06/10/2016

Actual: 06/10/2016

Data analysis start date
Planned: 07/11/2016

Actual: 10/10/2016

Date of final study report
Planned: 31/12/2016

Actual: 01/12/2016

Sources of funding

- Other

More details on funding

P95

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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Feasibility analysis

Data collection methods:

Primary data collection

Main study objective:

To assess whether reactogenicity data can be collected in a timely manner in Belgium, i.e. complete enrolment within one month after the start of vaccination in Belgium.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Alpharix Tetra

Medical condition to be studied

Immunisation reaction

Allergy to vaccine

Population studied

Short description of the study population

Subjects aged 18 to 65 years who had received inactivated seasonal influenza vaccine in occupational setting.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

100

Study design details

Outcomes

The number of days between start of vaccination campaign in Belgium and recruitment of 100 subjects. Enrolment rate (how man vaccinees have to be approached to reach 100 succesful enrolments), completion of follow-up.

Data analysis plan

Number of days between start of vaccination campaign in Belgium and complete enrolment.Enrolment rate.Rate of completion of follow-up.Rates of reactenogicity/ allergic events.

Documents

Study publications

Stuurman AL, Verstraeten T, De Schryver A. Rapid assessment of the reactogenici…

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)

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