Observational influenza vaccine active surveillance study: A Phase IV Prospective Multi-Centre Cohort Study to Evaluate the Reactogenicity of bioCSL's influenza virus vaccine (CSLCT-SAF-14-05)

First published: 22/08/2014

Last updated: 25/07/2016

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/14343

EU PAS number

EUPAS7301

Study ID

14343

DARWIN EU® study

No

Study countries

United Kingdom

Study description

To characterise the reactogenicity (local, systemic and allergic reactions) within seven days after each influenza vaccination with bioCSL’s influenza virus vaccine in participants routinely indicated for influenza vaccination in specified age groups.To assess the frequency and severity of medically attended adverse events with initial symptom onset within seven days after each influenza vaccination with bioCSL’s influenza virus vaccine.

Study status

Finalised

Research institutions and networks

Institutions

Harbinson House Surgery

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Harbinson House Surgery

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Knowle House Surgery PL5 3JB Plymouth, UK, The Rame Group Practice PL11 2JW Torpoint, UK, The Honiton Surgery Ward Practice EX14 2NY Honiton, Leicester Terrace Healthcare Centre NN2 6AL Northampton, Bradford on Avon Health Centre BA15 1DQ Bradford-on-Avon, Axbridge and Wedmore Medical Practice BS26 2BJ Axbridge, Harbinson House Surgery TS21 3BN Sedgefield, The Haven Surgery DH7 OBD Burnhope, University of Nottingham Health Service NG7 2QW Nottingham, East Quay Medical Centre TA6 4GP Bridgwater

Networks

NIHR Medicines for Children Research Network

First published: 01/02/2024

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Network

Contact details

Study institution contact

David Bibby

Study contact

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Primary lead investigator

James Larcombe

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/07/2014

Actual: 18/07/2014

Study start date

Planned: 01/10/2014

Actual: 03/10/2014

Data analysis start date

Planned: 09/10/2014

Actual: 24/10/2014

Date of interim report, if expected

Planned: 30/10/2014

Actual: 03/11/2014

Date of final study report

Planned: 05/02/2016

Actual: 11/02/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

bioCSL GmbH

Study protocol

CSLCT-SAF-14-05_PASS Abstract_V1_4-AUG-14.pdf(111.97 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

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

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

1st: To characterise the reactogenicity (local, systemic and allergic reactions) within 7days after each influenza vaccination with bioCSL’s influenza virus vaccine in participants routinely indicated for influenza vaccination in specified age groups.2nd: To assess frequency & severity of medically attended adverse events with initial symptom onset within 7days after vaccination.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Enzira® (2014/15) Influenza vaccine (2014/15)

Population studied

Short description of the study population

This observational post-marketing study is designed to capture the population receiving bioCSL’s influenza virus vaccine regardless of age or health status in order to provide a picture of the safety profile in routine practice. Pregnant and immune-compromised participants, and children aged less than 5 are not excluded from this study if they have been administered bioCSL’s influenza virus vaccine as part of routine care, or inadvertently prior to enrolment in the study. The source of the population will be people who present to general practice for influenza vaccination, either through mass vaccination clinics or opportunistic vaccination during routine consultations for the influenza vaccination season, and have received bioCSL’s influenza virus vaccine.
Inclusion criteria: Population who received at least one vaccination of bioCSL’s influenza virus vaccine after 1 July 2014.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Immunocompromised

Pregnant women

Estimated number of subjects

400

Study design details

Outcomes

The reactogenicity of bioCSL's influenza virus vaccine will be assessed in the vaccinated cohort by summarising reports of solicited AEs occurring within 7days after each vaccination. Solicited events include injection site, systemic and allergic reactions in all age groups. Participants will also be asked to indicate if they did not experience any AEs, to distinguish between no report reported AE, Information on medically attended AEs will be recorded for medical attendances that relate to events where the symptoms relating to the reason for medical attendance started within seven days after each influenza vaccination, even if the first attendance occurred outside the seven day period.

Data analysis plan

Descriptive analyses (frequencies, counts, n and percentages) will provide the majority of the results, both broken down into the four age groups and overall. Additional descriptive statistics (mean, standard deviation, median, range) are provided for continuous variables.

Documents

Study results

RESULT SUMMARY for CSLCT-SAF-14-05 - Final_10Aug15.pdf(88.73 KB)

Data management

ENCePP Seal

Signed checklist for study protocols

CSLCT-SAF-14-05_PASS protocol_4-AUG-14_Annex 2 ENCePP checklist.pdf (205.96 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Data collection will utilise a mix of investigator site data entry and participant (or parent/guardian) self-reported data entry into a web-accessed electronic database meeting appropriate observational research, regulatory and data protection standards.

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