Vaccine Effectiveness, Burden and Impact Studies (VEBIS), Vaccine effectiveness against COVID-19 and seasonal influenza among patients presenting to primary care physicians in EU/EEA

First published: 04/04/2024

Last updated: 03/04/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000095

Study ID

1000000095

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany

- [ ] Hungary
- [ ] Ireland
- [ ] Netherlands
- [ ] Portugal
- [ ] Romania
- [ ] Spain
- [ ] Sweden

Study description

Primary care systems offer the opportunity to conduct vaccine effectiveness studies; ECDC has since 2007 commissioned annual influenza vaccine effectiveness studies against seasonal influenza in primary care settings. Since February 2022, leveraging previous efforts and experience, the VEBIS primary care network has conducted studies for the vaccine effectiveness of both seasonal influenza and COVID-19 against moderate disease.

Study status

Ongoing

Research institutions and networks

Institutions

European Centre for Disease Prevention and Control

EpiConcept

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Institution

Contact details

Study institution contact

Marlena Kaczmarek vpd.vpd@ecdc.europa.eu

Study contact

vpd.vpd@ecdc.europa.eu

Primary lead investigator

Esther Kiessling

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 19/10/2021

Study start date

Actual: 01/02/2022

Date of final study report

Planned: 31/10/2025

Sources of funding

- Other

More details on funding

Funded by European Centre for Disease Prevention and Control

Study protocol

Core protocol for ECDC studies of vaccine effectiveness against symptomatic laboratory-confirmed influenza or SARS-CoV-2 infection at primary care level.pdf (12.81 MB)

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 topic, other:

Vaccine effectiveness

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

At study site/country level: test-negative, case-control study design in primary care setting.
At European level: test-negative, case-control study design in primary care setting using pooled data from several countries.

Main study objective:

The primary objective is to measure, for each EU/EEA primary care study site participating in IVE and CVE studies, and for pooled analyses, the direct effect of influenza and COVID-19 vaccines overall and by vaccine product against symptomatic laboratory-confirmed influenza or SARS-CoV-2

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medicinal product name

BIMERVAX

COMIRNATY

JCOVDEN

NUVAXOVID

SPIKEVAX

VAXZEVRIA

Study drug International non-proprietary name (INN) or common name

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

COVID-19 VACCINE (RECOMBINANT, ADJUVANTED)

DAVESOMERAN

ELASOMERAN

IMELASOMERAN

RAXTOZINAMERAN

TOZINAMERAN

Anatomical Therapeutic Chemical (ATC) code

(J07BN) Covid-19 vaccines

Covid-19 vaccines

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

(J07BN02) covid-19, viral vector, non-replicating

covid-19, viral vector, non-replicating

(J07BN04) covid-19, protein subunit

covid-19, protein subunit

Medical condition to be studied

COVID-19

Influenza

Additional medical condition(s)

Influenza-like illness (ILI) or acute respiratory infection (ARI)

Population studied

Short description of the study population

The study population comprises of community-dwelling individuals with symptoms of influenza-like illness (ILI) or acute respiratory infection (ARI) and no contraindication for influenza/COVID-19 vaccination, who consult a participating study physician.

Age groups

- **Paediatric Population (< 18 years)**
  - Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

The study population comprises community-dwelling individuals who present to participating physicians in the primary care setting, with symptoms meeting the case definition of their influenza or COVID-19 surveillance system, with no contraindications for influenza vaccination (for IVE) or COVID-19 vaccination (for CVE). The study period for seasonal IVE starts when the seasonal influenza vaccine of the corresponding season becomes available and the influenza season begins in the country/region, and will finish at the end of the influenza period. Cases and controls are included from the week of onset of the first influenza positive case presenting in each country-specific study.

The study period for CVE starts when the COVID-19 vaccine is available for the target group of interest in each of the participating countries and when SARS-CoV-2 is circulating. The study period is defined for each priority vaccination group, and begins for each vaccination group, when vaccination campaign in this group begins.

Physicians in participating primary care practices recruit patients and collect data throughout the year.

Outcomes

IVE studies

The primary outcome of interest will be PCR laboratory-confirmed influenza in symptomatic patients of all ages consulting at primary care level. The specific outcomes of interest are:

• subtype-specific laboratory-confirmed influenza A;

• laboratory-confirmed influenza B overall and, if available, by lineage (B Victoria/B Yamagata); and

• laboratory-confirmed influenza by clade/genetic variant (where possible).

CVE studies

The primary outcome of interest will be PCR laboratory-confirmed SARS-CoV-2 in symptomatic patients of all ages consulting at primary care level. Confirmation with rapid-diagnostic tests can be considered if highly specific and sensitive tests are used (see section 3.6 on ‘laboratory methods’).
Secondary outcomes of interest, in the same patient group at primary care level, will be genetic variants of SARS-CoV-2.

Data analysis plan

See protocol: https://www.ecdc.europa.eu/sites/default/files/documents/Core-protocol-ECDC-COVID-19-vaccine-studies-october2023.pdf

Documents

Study publications

Interim 2022/23 influenza vaccine effectiveness: six European studies, October …

Interim 2023/24 influenza A vaccine effectiveness: VEBIS European primary care …

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.

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