Effectiveness of Pfizer-BioNTech COVID-19 mRNA vaccine against severe illness in the elderly in Finland (RWE_COVID19_2023)

First published: 10/12/2024

Last updated: 29/04/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000376

Study ID

1000000376

DARWIN EU® study

No

Study countries

☐ Finland

Study description

The objective is to study the effectiveness of Pfizer-BioNTech COVID-19 mRNA vaccine against severe COVID-19 disease in the elderly by using real-world data collected in population-based national health registers in Finland.

Study status

Ongoing

Research institutions and networks

Institutions

FVR – Finnish Vaccine Research

Finland

First published: 21/03/2024

Last updated: 15/11/2024

Institution **Hospital/Clinic/Other health care facility**

Laboratory/Research/Testing facility

Contact details

Study institution contact

Annika Saukkoriipi annika.saukkoriipi@fvr.fi

Study contact

annika.saukkoriipi@fvr.fi

Primary lead investigator

Arto Palmu

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/11/2023

Study start date

Actual: 15/05/2024

Date of final study report

Planned: 31/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc.

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

A population-based nationwide cohort study using Finnish health registers.

Main study objective:

To estimate the effectiveness of the Pfizer-BioNTech COVID-19 mRNA vaccine booster in preventing COVID-19-related hospital admission in the community-dwelling elderly.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

COMIRNATY

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

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

Anatomical Therapeutic Chemical (ATC) code

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

Medical condition to be studied

COVID-19

COVID-19 pneumonia

Hospitalisation

Population studied

Short description of the study population

Elderly adults 65 years of age and older living in Finland.

Age groups

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Elderly

Estimated number of subjects

1300000

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 source(s)

Terveydenhuollon hoitoilmoitusrekisteri (Finland Care Register for Health Care)

Lääketoimitukset (Kanta - Reseptikeskus)

Data source(s), other

Other Finnish nationwide registers

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug prescriptions

Drug registry

Electronic healthcare records (EHR)

Non-interventional study

Population registry

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