# VidPrevtyn Beta® vaccine effectiveness against COVID-19 hospitalisations in the UK

Submission date	Recruitment status	Prospectively registered
20/07/2023	No longer recruiting	[X] Protocol
Registration date	Overall study status	Statistical analysis plan
24/07/2023	Completed	Results
Last Edited	Condition category	Individual participant data
12/09/2024	Infections and Infestations	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Background and study aims

This study aims to assess the vaccine effectiveness of VidPrevtyn Beta as a booster vaccine against severe COVID-19-related outcomes. This study additionally will assess the effectiveness of the vaccine in at-risk populations such as immunocompromised individuals, the elderly, and pregnant women (pending data availability).

### Who can participate?

This study will use a series of de-identified patient datasets in England, accessible through National Health Service (NHS) England (formerly known as NHS Digital).

#### What does the study involve?

The data analysed will start on March 1, 2018, and end at the time of data extraction (i.e., the latest day of data overlap across required datasets). Two campaign periods will be assessed for this study: The spring campaign and the autumn campaign. Three cohorts will be constituted for both vaccine campaign periods:

- 1. VidPrevtyn Boosted Cohort: Patients who received VidPrevtyn Beta during the campaign
- 2. Boosted Cohort: Patients who received another vaccine other than VidPrevtyn Beta during the campaign
- 3. Un-Boosted Cohort: Patients who did not receive any vaccine during the campaign Individuals in the VidPrevtyn Boosted Cohort will be matched to those in the Un-boosted Cohort. The follow-up period will begin on the index date and end at the earliest of death, the new vaccine, the outcome of interest, or 6-months after the index date. The index date for the VidPrevtyn Boosted Cohort will be 14 days after receiving the vaccine. The index date for the Un-Boosted Cohort will be the same date as their matched VidPrevtyn Boosted counterpart. Hazard Ratios (HR) of COVID-19-related hospitalization or COVID-19-related death following matching will be performed. Vaccine effectiveness (VE) will be calculated per each outcome. Analyses will be performed for the entire sample, as well as stratified by a selected set of measures which may include, age group, time since last vaccine dose immunocompromised status; groups at a greater risk of poor COVID-19 outcomes (e.g., immunosuppressed, liver cirrhosis, Down's syndrome, diabetes mellitus), pregnancy status. Individuals in the VidPrevtyn Boosted Cohort will also be matched to those in the Boosted Cohort. HR and VE estimates will be calculated using the same methodology as described previously.

Where is the study run from? Evidera (USA)

When is the study starting and how long is it expected to run for? January 2023 to March 2025

Who is funding the study? Sanofi Pasteur (France)

Who is the main contact?

Dr Mark Yates, mark.yates@evidera.com (UK)

# Contact information

### Type(s)

Principal investigator

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# Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

Nil known

# Study information

#### Scientific Title

VidPrevtyn Beta® vaccine effectiveness against hospitalization due to SARS-CoV-2 infection – a secondary database study in the UK

# **Study objectives**

This is an observational study. It is anticipated that the findings from this study will:

- 1. Enhance the understanding of vaccine effectiveness of VidPrevtyn Beta as a booster vaccine against severe COVID-19-related outcomes
- 2. Help assess the effectiveness of the vaccine in at-risk populations such as immunocompromised individuals, the elderly and pregnant women.

# Ethics approval required

Ethics approval not required

# Ethics approval(s)

The Health Research Authority (HRA) tool was used to assess the need for HRA approval. HRA approval is not required as this study utilized deidentified data and does not include any contact with patients or subjects.

# Study design

Observational retrospective matched cohort study

# Primary study design

Observational

# Study type(s)

**Efficacy** 

# Health condition(s) or problem(s) studied

COVID-19

#### **Interventions**

This is an observational retrospective matched cohort study using a series of datasets in England, accessible through National Health Services (NHS) England (formerly NHS Digital).

The overall study population will consist of individuals in England that were ≥18 years of age as of March 1, 2023. The study period will begin on April 1, 2018, and end six months after the end of the autumn 2023/2024 booster campaign (the study end date is the end of June 2024). Two campaign periods will be assessed for this study: The Spring campaign and the autumn campaign.

Three cohorts will be constituted for both vaccine campaign periods:

- 1. VidPrevtyn Boosted Cohort: Patients who received VidPrevtyn Beta during the campaign
- 2. Boosted Cohort: Patients who received another vaccine other than VidPrevtyn Beta during the campaign
- 3. Un-Boosted Cohort: Patients who did not receive any vaccine during the campaign

Individuals in the VidPrevtyn Boosted Cohort will be matched to those in the Un-boosted Cohort. The follow-up period will begin on the index date and end at the earliest of death, another COVID-19 vaccine administered, the outcome of interest, or 6-months after the index date. The index date for the VidPrevtyn Boosted Cohort will be 14 days after receiving the vaccine. The index date for the Un-Boosted Cohort will be the same date as their matched VidPrevtyn Boosted counterpart. Hazard Ratios (HR) of COVID-19-related hospitalization or COVID-19-related death following matching will be estimated. Vaccine effectiveness (VE) will be calculated per each outcome. Analyses will be performed for the entire sample, as well as stratified by a selected set of measures which may include, age group, time since last vaccine dose, immunocompromised status; groups at a greater risk of poor COVID-19 outcomes (e.g., immunosuppressed, liver cirrhosis, Down's syndrome, diabetes mellitus), pregnancy status. Individuals in the VidPrevtyn Boosted Cohort will also be matched to those in the Boosted Cohort. HR and VE estimates will be calculated as described above.

### **Intervention Type**

Drug

#### Phase

Not Applicable

# Drug/device/biological/vaccine name(s)

VidPrevtyn Beta

### Primary outcome(s)

Vaccine effectiveness of VidPrevtyn Beta against hospitalisation due to laboratory-confirmed SARS-CoV-2 infection in patients who have received at least one additional dose of VidPrevtyn Beta as their last dose, compared with patients who have not received a booster dose measured using patient medical records within the same campaign period

### Key secondary outcome(s))

Secondary outcome measures are measured using patient medical records:

- 1. Vaccine effectiveness of VidPrevtyn Beta against death due to laboratory-confirmed SARS-CoV-2 infection in patients who have received at least one additional dose of VidPrevtyn Beta as their last dose, compared with patients who have not received a booster dose within the same campaign period
- 2. Relative vaccine effectiveness of VidPrevtyn Beta against hospitalisation due to laboratory-confirmed SARS-CoV-2 infection in patients who have received at least one additional dose of VidPrevtyn Beta as their last dose, compared with patients who have received an mRNA booster dose within the same campaign period

# Exploratory outcome measures:

- 1. Vaccine effectiveness of VidPrevtyn Beta against hospitalisation due to laboratory-confirmed SARS-CoV-2 infection in patients who have received at least one additional dose of VidPrevtyn Beta as their last dose, compared with patients who have not received a booster dose within the same campaign period, stratified by:
- 1.1. Age groups
- 1.2. Gender
- 1.3. COVID-19 vaccination history
- 1.3.1. Compare by heterologous vs homologous (platform) history of vaccination
- 1.3.2. Compare by number of previous COVID-19 vaccine doses received
- 1.3.3. Subgroups of special interest (e.g. pregnant women, immunocompromised patients, frail patients with unstable health conditions and co-morbidities (eg, chronic obstructive pulmonary disease [COPD], diabetes, chronic neurological disease, cardiovascular disorders), patients with the autoimmune or inflammatory disorder)

#### Completion date

01/03/2025

# **Eligibility**

#### Key inclusion criteria

This study will include all individuals aged 18 years or older who are eligible to receive a VidPrevtyn Beta vaccine.

#### Participant type(s)

Αll

#### Healthy volunteers allowed

No

#### Age group

Mixed

#### Lower age limit

1	8	years	S
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#### Sex

All

# Key exclusion criteria

Individuals <18 years and those who are ineligible to receive a VidPrevtyn Beta vaccine.

#### Date of first enrolment

01/03/2023

#### Date of final enrolment

31/12/2023

# Locations

# Countries of recruitment

United Kingdom

England

# Study participating centre

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United Kingdom

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# Sponsor information

# Organisation

Sanofi (France)

#### **ROR**

https://ror.org/02n6c9837

# Funder(s)

# Funder type

Industry

#### Funder Name

Sanofi Pasteur

### Alternative Name(s)

# Funding Body Type

Private sector organisation

# **Funding Body Subtype**

For-profit companies (industry)

#### Location

France

# **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available. The data obtained from NHS England for this study will be accessed via a secure data environment (SDE), managed by NHSE. Access to the 'raw data' would therefore need to be requested from NHSE. Evidera does not hold or manage this data in-house, and thus cannot make this data publicly available.

## IPD sharing plan summary

Not expected to be made available

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<u>Protocol file</u>	Synopsis	15/06/2023	24/07/2023	No	No