

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

<b>Submission date</b> 20/07/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/07/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/09/2024	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study aims to assess the vaccine effectiveness of VidPrevtyl 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. VidPrevtyl Boosted Cohort: Patients who received VidPrevtyl Beta during the campaign
2. Boosted Cohort: Patients who received another vaccine other than VidPrevtyl Beta during the campaign
3. Un-Boosted Cohort: Patients who did not receive any vaccine during the campaign

Individuals in the VidPrevtyl 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 VidPrevtyl 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 VidPrevtyl 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 VidPrevtyl 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

### Contact name

Dr Mark Yates

### ORCID ID

<https://orcid.org/0000-0001-5449-5211>

### Contact details

The Ark  
Talgarth Road  
Hammersmith  
London  
United Kingdom  
W6 8BJ  
None provided  
mark.yates@evidera.com

### Type(s)

Scientific

### Contact name

Dr Mark Yates

### Contact details

The Ark  
Talgarth Road  
Hammersmith  
London  
United Kingdom  
W6 8BJ  
None provided  
mark.yates@evidera.com

### Type(s)

Public

**Contact name**

Dr Mark Yates

**Contact details**

The Ark  
Talgarth Road  
Hammersmith  
London  
United Kingdom  
W6 8BJ  
None provided  
mark.yates@evidera.com

**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  $\geq 18$  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. VidPrevtyl Boosted Cohort: Patients who received VidPrevtyl Beta during the campaign
2. Boosted Cohort: Patients who received another vaccine other than VidPrevtyl Beta during the campaign
3. Un-Boosted Cohort: Patients who did not receive any vaccine during the campaign

Individuals in the VidPrevtyl 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 VidPrevtyl 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 VidPrevtyl 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 VidPrevtyl 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)

VidPrevtyl Beta

## Primary outcome(s)

Vaccine effectiveness of VidPrevtyl Beta against hospitalisation due to laboratory-confirmed SARS-CoV-2 infection in patients who have received at least one additional dose of VidPrevtyl 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 VidPrevtyl Beta against death due to laboratory-confirmed SARS-CoV-2 infection in patients who have received at least one additional dose of VidPrevtyl 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 VidPrevtyl Beta against hospitalisation due to laboratory-confirmed SARS-CoV-2 infection in patients who have received at least one additional dose of VidPrevtyl 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 VidPrevtyl Beta against hospitalisation due to laboratory-confirmed SARS-CoV-2 infection in patients who have received at least one additional dose of VidPrevtyl 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 VidPrevtyl Beta vaccine.

### **Participant type(s)**

All

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Individuals <18 years and those who are ineligible to receive a VidPrevtyl 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**

-

United Kingdom

-

**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?
<a href="#">Protocol file</a>	Synopsis	15/06/2023	24/07/2023	No	No