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

Submission date
20/07/2023

Recruitment status
No longer recruiting

Registration date
24/07/2023

Overall study status
Completed

Last Edited
12/09/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Medical and other records

Study type(s)
Efficacy

Participant information sheet
No participant information sheet available

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

Pharmaceutical study type(s)
Vaccine effectiveness study

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
VidPrevtyn Beta

Primary outcome measure
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

Secondary outcome measures
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)

Overall study start date
01/01/2023

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)
All

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
617,000

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
England

United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
Sanofi (France)

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Sponsor type
Industry

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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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/03/2026

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?
Protocol file	Synopsis	15/06/2023	24/07/2023	No	No