COVID-19 is an emerging, rapidly evolving situation.

Public health information (CDC)

Research information (NIH)

SARS-CoV-2 data (NCBI)

Prevention and treatment information (HHS)

A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants (ENSEMBLE)

ClinicalTrials.gov Identifier: NCT04505722

Recruitment Status : Active, not recruiting
First Posted : August 10, 2020
Last Update Posted : February 9, 2021

Sponsor:
Janssen Vaccines & Prevention B.V.

Information provided by (Responsible Party):
Janssen Vaccines & Prevention B.V.

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

Go to

Brief Summary:

The study will enroll approximately 40,000 participants in order to evaluate the efficacy of Ad26.COV2.S in the prevention of molecularly confirmed moderate to severe/critical COVID-19, as compared to placebo, in adult participants.

Condition or disease	Intervention/treatment	Phase
Participants With or Without Stable Co-morbidities Associated With Progression to Severe COVID-19 at Different Stages of the Protocol	Biological: Ad26.COV2.S Other: Placebo	Phase 3

Study Design

Go to

Study Type :

Interventional (Clinical Trial)

Actual Enrollment :

44325 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Masking:

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose:

Prevention

Official Title:

A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older

Actual Study Start Date :

September 7, 2020

Actual Primary Completion Date :

January 22, 2021

Estimated Study Completion Date :

January 2, 2023

Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: Ad26.COV2.S Participants will receive intramuscular (IM) injection of Ad26.COV2.S at a dose level of 5*10^10 virus particles (vp) as single dose vaccine on Day 1.	Biological: Ad26.COV2.S Ad26.COV2.S will be administered at a dose level of 5*10^10 virus particles (vp) as single dose vaccine on Day 1. Other Names: • JNJ-78436735 • Ad26COVS1
Placebo Comparator: Placebo Participants will receive IM injection of placebo on Day 1.	Other: Placebo Participants will receive Placebo.

Outcome Measures

Go to

Primary Outcome Measures :

1. Number of Participants with First Occurrence of Molecularly Confirmed Moderate to Severe/Critical Coronavirus Disease (COVID-19) with Seronegative Status [Time Frame: 14 Days post-vaccination (Day 15) to end of study (2 years and 1 month)]

   Moderate defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate greater than or equal to (>=) 20 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

2. Number of Participants with First Occurrence of Molecularly Confirmed Moderate to Severe/Critical Coronavirus Disease (COVID-19) with Seronegative Status [Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]

   Moderate defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate greater than or equal to (>=) 20 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

Secondary Outcome Measures :

1. Number of Participants with First Occurrence of Molecularly Confirmed Severe/Critical Coronavirus Disease (COVID-19) with Seronegative Status [Time Frame: 14 Days post-vaccination (Day 15) to end of study (2 years and 1 month)]

Severe defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate greater than or equal to (>=) 30 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

2. Number of Participants with First Occurrence of Molecularly Confirmed Severe/Critical Coronavirus Disease (COVID-19) with Seronegative Status [Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]

   Severe defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate greater than or equal to (>=) 30 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

3. Number of Participants with First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 Regardless of their Serostatus [Time Frame: 1 Day post-vaccination (Day 2) to end of study (2 years and 1 months)]

   Moderate defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate >= 20 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

4. Number of Participants with First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 Regardless of their Serostatus [Time Frame: 14 days post-vaccination (Day 15) up to end of study (2 years and 1 month)]

   Moderate defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate >= 20 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

5. Number of Participants with First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 Regardless of Their Serostatus [Time Frame: 28 days post-vaccination (Day 15) up to end of study (2 years and 1 month)]

   Moderate defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate greater than or equal to (>=) 20 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

6. Number of Participants with First Occurrence of COVID-19 Requiring Medical Intervention [Time Frame: 14 days post-vaccination (Day 15) up to end of study (2 years and 1 month)]

Number of participants with first occurrence of COVID-19 requiring medical intervention (such as a composite endpoint of hospitalization, intensive care unit (ICU) admission, mechanical ventilation, and extracorporeal membrane oxygenation (ECMO), linked to objective measures such as decreased oxygenation, X-ray or CT findings) or linked to any molecularly confirmed, COVID-19 at least 14 days post vaccination will be reported.

7. Number of Participants with First Occurrence of COVID-19 Requiring Medical Intervention
[Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]

   Number of participants with first occurrence of COVID-19 requiring medical intervention (such as a composite endpoint of hospitalization, intensive care unit (ICU) admission, mechanical ventilation, and extracorporeal membrane oxygenation (ECMO), linked to objective measures such as decreased oxygenation, X-ray or CT findings) or linked to any molecularly confirmed, COVID-19 at least 28 days post vaccination will be reported.

8. SARS-CoV-2 Viral Load as Assessed by Quantitative Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) in Participants with Molecularly Confirmed, Moderate to Severe/Critical COVID-19 [Time Frame: 14 Days post-vaccination (Day 15) to end of study (2 years and 1 month)]

   The viral load of SARS-CoV-2 will be assessed in confirmed COVID-19 cases using RT-PCR. Nasal swabs will be used to detect and/or quantify SARS-CoV-2.

9. Number of Participants with First Occurrence of Molecularly Confirmed Mild COVID-19
[Time Frame: 14 Days post-vaccination (Day 15) to end of study (2 years and 1 month)]

   Molecularly confirmed mild COVID-19 is defined as a SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (example, nasal swab sample, sputum sample, throat swab sample, saliva sample) or other sample. Mild COVID-19 includes: Fever, sore throat, malaise, headache, muscle pain, gastrointestinal symptoms, cough, chest congestion, runny nose, wheezing, skin rash, eye irritation or discharge, or chills, without shortness of breath or dyspnea.

10. Number of Participants with First Occurrence of Molecularly Confirmed Mild COVID-19
[Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]

    Molecularly confirmed mild COVID-19 is defined as a SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (example, nasal swab sample, sputum sample, throat swab sample, saliva sample) or other sample. Mild COVID-19 includes: Fever, sore throat, malaise, headache, muscle pain, gastrointestinal symptoms, cough, chest congestion, runny nose, wheezing, skin rash, eye irritation or discharge, or chills, without shortness of breath or dyspnea.

11. Number of Participants with First Occurrence of Molecularly Confirmed COVID-19 Defined by the US Food and Drug Administration (FDA) Harmonized case Definition [Time Frame: 14 Days post-vaccination (Day 15) to end of study (2 years and 1 month)]

    Molecularly confirmed moderate and severe/critical COVID-19 defined as a positive SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (example, nasal swab sample, sputum sample, throat swab sample, saliva sample) or other sample; and COVID-19 symptoms consistent with those defined by the US FDA harmonized case Definition at the time of finalization of this protocol: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea.

12. Number of Participants with First Occurrence of Molecularly Confirmed COVID-19 Defined by the US Food and Drug Administration (FDA) Harmonized case Definition [Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]

    Molecularly confirmed moderate and severe/critical COVID-19 defined as a positive SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (example, nasal swab sample, sputum sample, throat swab sample, saliva sample) or other sample; and COVID-19 symptoms consistent with those defined by the US FDA harmonized case Definition at the time of finalization of this protocol: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea.

13. Burden of Disease (BOD) Based on First Occurrence of Molecularly Confirmed Symptomatic COVID-19 [Time Frame: 14 Days post-vaccination (Day 15) to end of study (2 years and 1 month)]

    BOD will be evaluated based on the first occurrence of molecularly confirmed COVID-19, including mild, moderate or severe/critical COVID-19 case.

14. BOD Based on First Occurrence of Molecularly Confirmed Symptomatic COVID-19 [Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]

    BOD will be evaluated based on the first occurrence of molecularly confirmed COVID-19, including mild, moderate or severe/critical COVID-19 case.

15. Serologic Conversion Between Baseline and (Day 1; Pre-vaccination), Day 71, 6 Months and 1-Year Post-vaccination using an Enzyme-linked Immunosorbent Assay (ELISA)
    [Time Frame: Between baseline (Day 1; pre-vaccination) and Day 71, 6 Months, 1-Year post-vaccination (up to 52 Weeks)]

    Serologic conversion between baseline and (Day 1; pre-vaccination), Day 71, 6 Months, 1 year post-vaccination using an ELISA and/or SARS-CoV- 2 immunoglobulin assay that is dependent on the

SARS-CoV-2 nucleocapsid (N) protein will be reported.

16. Number of Participants with First Occurrence of SARS-CoV-2 Infection (Serologically and/or Molecularly Confirmed) [Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]

    Number of participants with first occurrence of SARS-CoV-2 infection (serologically and/or molecularly confirmed) with onset at least 28 days after vaccination (Day 29) to end of Study (2 years and 1 month) will be reported.

17. Number of Participants with Serious Adverse Events (SAEs) [Time Frame: Up to 104 Weeks]

    SAE is any untoward medical occurrence that at any dose may result in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission of any infectious agent via a medicinal product.

18. Number of Participants with Medically-Attended Adverse Events (MAAEs) [Time Frame: Up to 6 Months]

    MAAEs are defined as AEs with medically-attended visits including hospital, emergency room, urgent care clinic, or other visits to or from medical personnel for any reason.

19. Number of Participants with Medically-Attended Adverse Events (MAAEs) Leading to Study Discontinuation [Time Frame: Up to 104 Weeks]

    MAAEs are defined as AEs with medically-attended visits including hospital, emergency room, urgent care clinic, or other visits to or from medical personnel for any reason. Routine study visits will not be considered medically-attended visits. New onset of chronic diseases will be collected as part of the MAAEs.

20. Number of Participants with Solicited Local Adverse Events (AEs) During 7 Days Following Vaccination [Time Frame: Up to Day 8 (7 Days after first vaccination on Day 1)]

    Participants who will be enrolled in safety subset will be asked to note in the e-Diary occurrences of injection site pain/tenderness, erythema, and swelling at the study vaccine injection site daily for 7 days post-vaccination (day of vaccination and the subsequent 7 days).

21. Number of Participants with Solicited Systemic AEs During 7 Days Following Vaccination [Time Frame: Up to Day 8 (7 Days after first vaccination on Day 1)]

    Participants who will be enrolled in safety subset will be instructed on how to record daily temperature using a thermometer provided for home use. Participants should record the

temperature in the e-Diary in the evening of the day of vaccination, and then daily for the next 7 days approximately at the same time each day. If more than 1 measurement is made on any given day, the highest temperature of that day will be recorded in the e-Diary. Fever is defined as endogenous elevation of body temperature >= 38.0 degree Celsius or >=100.4-degree Fahrenheit, as recorded in at least 1 measurement. Participants will also be instructed on how to note signs and symptoms in the e-Diary on a daily basis for 7 days post-vaccination (day of vaccination and the subsequent 7 days), for the following events: fatigue, headache, nausea, myalgia.

22. Number of Participants with Unsolicited Local Adverse Events (AEs) During 28 Days Post-vaccination [Time Frame: Up to Day 29 (28 Days after first vaccination on Day 1)]

    Unsolicited AEs are all AEs for which the participant is not specifically questioned in the participant diary.

23. SARS-CoV-2 Neutralizing Antibody Titers as Assessed by Virus Neutralization Assay (VNA) [Time Frame: Up to 104 Weeks]

    Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) neutralizing antibody titers as assessed by VNA to measure the humoral immune responses will be reported

24. SARS-CoV-2 Binding Antibodies Assessed by ELISA [Time Frame: Up to 104 Weeks]

    SARS-CoV-2 binding antibodies as assessed by enzyme-linked immunosorbent assay (ELISA) to measure humoral immune response will be reported.

Eligibility Criteria

Go to

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

Yes

Criteria

Inclusion Criteria:

- Contraceptive (birth control) use should be consistent with local regulations regarding the acceptable methods of contraception for those participating in clinical studies
- All participants of childbearing potential must: have a negative highly sensitive urine pregnancy test at screening; and have a negative highly sensitive urine pregnancy test immediately prior to each study vaccine administration
- Participant agrees to not donate bone marrow, blood, and blood products from the first study vaccine administration until 3 months after receiving the last dose of study vaccine
- Must be willing to provide verifiable identification, has means to be contacted and to contact the investigator during the study
- Must be able to read, understand, and complete questionnaires in the electronic clinical outcome assessment (eCOA) (that is, the coronavirus disease-2019 [COVID 19] signs and symptoms surveillance question, the e-Diary, and the electronic patient-reported outcomes (ePROs). Note: Participants with visual impairment are eligible for study participation and may have caregiver assistance in completing the electronic clinical outcome assessment (eCOA) questionnaires

Exclusion Criteria:

- Participant has a clinically significant acute illness (this does not include minor illnesses such as diarrhea or mild upper respiratory tract infection) or temperature greater than or equal to (>=) 38.0 degree Celsius (100.4-degree Fahrenheit) within 24 hours prior to the planned first dose of study vaccine; randomization at a later date is permitted at the discretion of the investigator and after consultation with the sponsor
- Participant received or plans to receive: (a) licensed live attenuated vaccines - within 28 days before or after planned administration of study vaccine ; and (b) other licensed (not live) vaccines - within 14 days before or after planned administration of study vaccine
- Participant previously received a coronavirus vaccine
- Participant received an investigational drug (including investigational drugs for prophylaxis of COVID-19) within 30 days or used an invasive investigational medical device within 30 days or received investigational immunoglobulin or monoclonal antibodies within 3 months, or received convalescent serum for COVID-19 treatment within 4 months or received an investigational vaccine (including investigational Adenoviral-vectored vaccines) within 6 months before the planned administration of the first dose of study vaccine or is currently enrolled or plans to participate in another investigational study during the course of this study

Contacts and Locations

Go to

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04505722***

Locations

▶ Show 213 study locations

Sponsors and Collaborators

Janssen Vaccines & Prevention B.V.

Investigators

Study Director: Janssen Vaccines & Prevention B.V. Clinical Trial Janssen Vaccines & Prevention B.V.

More Information

Go to

Additional Information:

To learn how to participate in this trial please click here.

Responsible Party:

Janssen Vaccines & Prevention B.V.

ClinicalTrials.gov Identifier:

NCT04505722 History of Changes

Other Study ID Numbers:

CR108876

VAC31518COV3001 (Other Identifier: Janssen Vaccines & Prevention B.V.)

First Posted:

August 10, 2020 Key Record Dates

Last Update Posted:

February 9, 2021

Last Verified:

February 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

Yes

Plan Description:

The data sharing policy of the Janssen Pharmaceutical Companies of Johnson & Johnson is available at www.janssen.com/clinical-trials/transparency. As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site at yoda.yale.edu

URL:

https://www.janssen.com/clinical-trials/transparency

Studies a U.S. FDA-regulated Drug Product:

Yes

Studies a U.S. FDA-regulated Device Product:

No

Keywords provided by Janssen Vaccines & Prevention B.V.:

Prevention

Vaccine

Additional relevant MeSH terms:

Disease Progression

Disease Attributes

Pathologic Processes