A Randomized, Double-blind, Placebo-controlled Phase 2a Study to Evaluate a Range of Dose Levels and Vaccination Intervals of Ad26.COV2.S in Healthy Adults Aged 18 to 55 Years Inclusive and Adults Aged 65 Years and Older and to Evaluate 2 Dose Levels of Ad26.COV2.S in Healthy Adolescents Aged 12 to 17 Years Inclusive

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The primary purpose of this study is to assess humoral immune responses of 3 dose levels of Ad26.COV2.S administered intramuscularly (IM) as a 2-dose schedule (56 days apart); Ad26.COV2.S administered IM as a single vaccination; safety and...

Ethical review	Approved WMO
Status	Completed
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON55105

Source
ToetsingOnline

Brief title
VAC31518COV2001

Condition

- Viral infectious disorders

Synonym
coronavirus, SARS-CoV-2

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Janssen-Cilag BV & BARDA funding

Intervention

Keyword: Coronavirus, COVID-19, SARS-COV-2, Vaccine

Outcome measures

Primary outcome

Adults:

- Serological response to vaccination as measured by virus neutralization assay

(VNA) titers and enzyme-linked immunosorbent assay (ELISA), 28days after

Vaccination 2.

- Antibody geometric mean titers (GMTs) and geometric mean concentrations

(GMCs), 28days after Vaccination 2.

- Serological response to vaccination as measured by VNA titers and ELISA,

28days after Vaccination 1.

- Antibody GMTs and GMCs, 28days after Vaccination 1.

- Serological response to vaccination as measured by VNA titers and ELISA,

28days after Vaccination 2.

- Antibody GMTs and GMCs, 28days after Vaccination 2

- Solicited local and systemic AEs for 7 days after each vaccination.

- Unsolicited AEs for 28 days after each vaccination.

- Serious adverse events (SAEs) and adverse events of special interest (AESIs) throughout the study (from first vaccination until end of the study).

Adolescents:

- Solicited local and systemic AEs for 7 days after each vaccination.

- Unsolicited AEs for 28 days after each vaccination.

- SAEs and AESIs throughout the study (from first vaccination until end of the study).

- Serological response to vaccination as measured by psVNA titer, 28 days post-dose 1

Secondary outcome

Adults:

- Serological response to vaccination as measured by VNA titers and ELISA, 7 days after antigen presentation.

- Antibody GMTs and GMCs, 7 days after antigen presentation.

- Solicited local and systemic AEs for 7 days after antigen presentation.

- Unsolicited AEs for 28 days after antigen presentation.

- SAEs and AESIs throughout the study (from antigen presentation until end of the study).

- Neutralizing antibody titers to the wild-type SARS-CoV-2 virus and/or pseudovirion expressing S protein as measured by VNA, at all blood collection timepoints

- Binding antibody titers to SARS-CoV-2 or individual SARS-CoV-2 proteins (eg, Sprotein) as measured by ELISA, at all blood collection timepoints.

Adolescents:

- Serological response to vaccination as measured by VNA titers and ELISA, 28 days after Vaccination.
- Antibody GMTs (VNA) and GMCs, 28 days after Vaccination.
- Serological response to vaccination as measured by VNA titers and ELISA, 7 days after the booster vaccination
- Antibody GMTs (VNA) and GMCs, 7 days after the booster vaccination.
- Solicited local and systemic AEs for 7 days after the booster vaccination
- Unsolicited AEs for 28 days after the booster vaccination
- SAEs and AESIs throughout the study (from booster dose until end of the study).

Study description

Background summary

The aim of the COVID-19 vaccine clinical development program is to develop a safe and effective vaccine for the prevention of COVID-19. Currently, there is only limited availability COVID-19 vaccines for which Emergency Use Authorization (EUA) or conditional licensure has been given.

Study objective

The primary purpose of this study is to assess humoral immune responses of 3 dose levels of Ad26.COV2.S administered intramuscularly (IM) as a 2-dose schedule (56 days apart); Ad26.COV2.S administered IM as a single vaccination; safety and reactogenicity of Ad26.COV2.S administered IM as a 2-dose or a single-dose schedule in adults (18-55 year and 65 years or older) and to assess

the safety and reactogenicity of Ad26.COV2.S, administered IM as single dose in adolescents (12-17 years) and to test both compressed and expanded 2-dose schedules of Ad26.COV2.S (28 and 84 days apart) in adults (18-55 years and 65 years or older).

Study design

This is a randomized, double-blind, placebo-controlled, multicenter, Phase 2a study in healthy adults aged 18 to 55 years inclusive, adults in good or stable health aged 65 years and older, and healthy adolescents aged 12 to 17 years inclusive.

Intervention

Adults:
Vaccination of Ad26.COV2.S in 1-and 2-dose vaccination regimens followed by antigen presentation after 4 months (2-dose regimen) or 6 months (single-dose regimen). Participants who received placebo will receive 2 doses of the Ad26.COV2.S vaccine with a 28-day interval.

Adolescents:
Vaccination of Ad26.COV2.S in a single dose vaccination regimen at Day 1 at fixed dose level or placebo.

Study burden and risks

The primary ethical concern is that this study will be performed in adult and adolescent participants who will receive no benefit from participation in the study, except for compensation for the time and inconveniences that may arise from participation in the study. The potential risk to adolescent participants in this study include study vaccine exposure, with the potential for AEs.

The clinical benefits of Ad26COVS1 have yet to be established. The overall benefit and risk balance for individual participants thus cannot be ascertained. Participants must be informed that this vaccine has not yet been proven to be effective, and it should be assumed that it is not the case until clinical studies are conducted to demonstrate its effectiveness.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

Adults:
1. Participant is 18 to 55 years of age, inclusive, or 65 years of age or older on the day of signing the ICF.
2. Participant must have a body mass index (BMI) <30.0 kg/m2.
3. Participant 18 to 55 years of age, inclusive: Participant must be healthy, in the investigator's clinical judgment, as confirmed by medical history, physical examination, and vital signs performed at screening, and must not have comorbidities related to an increased risk of severe COVID-19, except for smoking, which is allowed.
Participant 65 years of age and older: in the investigator's clinical judgment, participant must be either in good or stable health. Participant may have underlying illnesses, as long as the symptoms and signs are medically controlled and not considered to be comorbidities related to an increased risk of severe COVID-19, except for smoking, which is allowed. If on medication for a condition, the medication dose must have been stable for at least 12 weeks preceding vaccination and expected to remain stable for the duration of the study. Participant will

be included on the basis of physical examination, medical history, and vital signs.
4. All participants of childbearing potential must:
a. Have a negative highly sensitive urine pregnancy test at screening.
b. Have a negative highly sensitive urine pregnancy test immediately prior to each study vaccine administration.
5. 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.

Adolescents:
1.Participant is 12 to 17 years of age, inclusive, on the day of signing the ICF
2.Participant must be healthy, in the investigator's clinical judgment, as confirmed by medical history, physical examination, and vital signs performed at screening, and must not have comorbidities related to an increased risk of severe COVID-19
3.Contraceptive (birth control) use by women
4.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.

Exclusion criteria

Adults:
1. Participant has a clinically significant acute illness (this does not include minor illnesses such as diarrhea or mild upper respiratory tract infection) or temperature >=38.0ºC (100.4°F) 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.
2. Participant has a history of malignancy within 5 years before screening (exceptions are squamous and basal cell carcinomas of the skin and carcinoma in situ of the cervix, or malignancy, which is considered cured with minimal risk of recurrence).
3. Participant has a known or suspected allergy or history of anaphylaxis or other serious adverse reactions to vaccines or their excipients (including specifically the excipients of the study vaccine).
4. Participant has abnormal function of the immune system.
5. Participant has a history of any neurological disorders or seizures including Guillain-Barré syndrome, with the exception of febrile seizures during childhood.
6. Participant has a history of chronic urticaria (recurrent hives), eczema or adult atopic dermatitis.
7. Participant received treatment with immunoglobulins in the 3 months or blood products in the 4 months before the planned administration of the first dose of study vaccine or has any plans to receive such treatment during the study.

8. Participant is a woman who is pregnant, breastfeeding, or planning to become pregnant within 3 months after the last dose of study vaccine.
9. Participant has chronic active hepatitis B or hepatitis C infection per medical history.
10. Participant previously received a coronavirus vaccine.
11. Participant has a positive diagnostic test result for past (serological testing) or current (PCR based viral RNA detection) SARS-CoV-2 infection at screening.
12. Participants with comorbidities that are or might be associated with an increased risk of progression to severe COVID-19, ie, participants with moderate-to severe asthma; chronic lung diseases such as chronic obstructive pulmonary disease (COPD) (including emphysema and chronic bronchitis), idiopathic pulmonary fibrosis and cystic fibrosis;
diabetes (including type 1, type 2, or gestational); serious heart conditions, including heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension or high blood pressure; obesity (BMI >= 30 kg/m2); chronic liver disease,including cirrhosis; sickle cell disease; thalassemia; cerebrovascular disease; neurologic conditions (dementia); and participants who live in nursing homes or long-term care facilities. This list is consistent with the
list of conditions that increase the risk of progression to severe COVID19 available at the CDC website at the time of writing of this protocol, except for smoking, which is allowed.
Applicable only to participants 65 years of age and older: Participants may have hypertension of mild severity as long as it is stable and medically controlled as defined by no change in medication over the past 6 months (except for issues of tolerability or use of similar drug with same mechanism of action, eg, thiazides, Beta blockers, Alpha blockers at the same effective dose).
13. Participant who is currently working in an occupation with a high risk of exposure to SARS-CoV-2 infection (eg, health care worker or emergency response personnel who work in close contact with SARSCoV-2 infected patients) or considered at the investigator's discretion to
be at increased risk to acquire COVID-19 for any other reason.
14. Participant who has had a known exposure to an individual with confirmed COVID-19 or SARS-CoV-2 infection within the past 2 weeks.
15. History of confirmed SARS or MERS.

Adolescents:
1.Participant has a clinically significant acute illness (this does not include minor illnesses such as diarrhea or mild upper respiratory tract infection) or temperature >=38.0ºC (100.4°F) within 24 hours prior to the planned first dose of study vaccine
2.Participant has a history of malignancy within 5 years before screening
3. Participants who required chronic administration (defined as more than 14 days) of immunosuppressants or other immune-modifying drugs within 6 months prior to the study vaccination

4.Any serious, chronic, or progressive disease
5.Participant has obesity
6.Participant received treatment with immunoglobulins in the 3 months or blood products in the 4 months before the planned administration of the first dose of study vaccine or has any plans to receive such treatment during the study
7.Participant has chronic active hepatitis B or hepatitis C infection per medical history
8.Exposure to a person with confirmed COVID-19 or SARS-CoV-2 infection within the past 2 weeks
9.History of confirmed SARS or MERS

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-09-2020
Enrollment:	135
Type:	Actual

Ethics review

Approved WMO

Date:	06-08-2020
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO Date:	26-08-2020
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-09-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-10-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-11-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-11-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-11-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-02-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-06-2021
Application type:	Amendment

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-07-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-07-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	26-07-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
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Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	06-09-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	03-11-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-11-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2020-002584-63-NL
CCMO	NL74451.000.20

Study results

Date completed: 19-11-2021

Results posted: 06-03-2023

First publication
01-09-2022

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File