A phase 1, randomized, observer-blind study to compare the safety, reactogenicity, and Immunogenicity of Ad26.COV2.S at a single Dose of 5x10^10 vp in 2 different volumes in healthy adults

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

Summary

ID

NL-OMON50855

Source
ToetsingOnline

Brief title
Comparison of two different volumes of the Ad26.COV2.S vaccine

Condition

- Viral infectious disorders

Synonym
coronavirus, COVID-19

Research involving

Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Janssen Vaccines and Prevention BV

Intervention

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

Outcome measures

Primary outcome

1. To assess the safety and reactogenicity of Ad26.COV2.S 5x10^10 vp per 0.3 mL versus 5x10^10 vp per 0.5 mL.

2. To demonstrate non-inferiority (NI) of the immune responses (Geometric mean concentration (GMC)) 28 days after vaccination with Ad26.COV2.S 5x10^10 vp per 0.3 mL versus 5x10^10 vp per 0.5 mL, as measured by S enzyme-linked immunosorbent assay (S-ELISA) using a NI margin of 2/3 for the GMC ratio (GMC of 5x10^10 vp in 0.3 mL/GMC 5x10^10 vp in 0.5 mL).

Secondary outcome

1. To assess the humoral immune response to Ad26.COV2.S across both groups, at all blood collection timepoints.

2. To further assess the humoral immune response to Ad26.COV2.S in a subset of participants across both groups, at selected blood collection timepoints.

Study description

Background summary

This study is being done to test the vaccine called Ad26.COV2.S. Doctors and scientists hope it will prevent or lessen the severity of diseases caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). When the term *coronavirus* is used in this document, it refers to SARS CoV 2. This virus causes the disease called COVID-19. SARS-CoV-2 is passed from person to person primarily by small droplets from the nose or mouth when an infected person coughs, sneezes or speaks. Most people who are infected have mild disease such as cough and extreme tiredness, but some people have severe disease and have difficulty breathing and can even die from this disease.

A vaccine helps to prevent diseases and their spread by allowing the human body to form an immune response against what causes the disease, such as viruses or bacteria. This defensive response is a way your body fights infections. The immune response that Ad26.COV2.S causes is specific for SARS-CoV-2.

Ad26.COV2.S is made from a type of common cold virus called adenovirus. The adenovirus used to make this vaccine is harmless to people because it cannot multiply anymore.

The Ad26.COV2.S study vaccine includes genetic material from SARS-CoV-2 virus. When the study vaccine is injected into your body, the genetic material from SARS-CoV-2 gets *translated* to produce so called *spike proteins* which are specific to SARS-CoV-2. Our bodies recognize these proteins and make an immune response against them. You cannot contract COVID-19 from the study vaccine.

Given the plan to vaccinate a large portion of the global population, tremendous supplies of vaccine are needed. The purpose of this study is to determine if a greater number of vaccine doses can be contained in the same vial if the volume of the vaccine is reduced. This would have a positive impact on supply.

Ad26.COV2.S is already being used to vaccinate people in Europe, the United States, and Canada against SARS-CoV-2.

Study objective

Ad26.COV2.S, also referred to as a *study vaccine* in this document, is a COVID 19 vaccine. In this study, the formation of antibodies against the coronavirus is compared at two different dosing volumes. In addition, it will be investigated if it is safe, if it can cause side-effects (unexpected or unwanted reactions from taking a drug), and how well the study vaccine is tolerated by the healthy participants in the study.

Ad26.COV2.S will be tested in a fixed dose level but with two different injection volumes in healthy adults aged 18 to 65 years inclusive.

Ad26.COV2.S has been used by humans before and is currently authorized to be

used to vaccinate people in Europe, the United States, and Canada. The dose used in this study is the same as that used in the large scale phase 3 study and on the basis of which effectiveness has been demonstrated and authorization obtained. Both dose volumes contain the same dose of vaccine.

Study design

The study will take 6 months from the screening until the final visit. The study will consist of a 24-week study period (including administration of 1 dose of study vaccine and a 6-month follow-up period). In total the volunteers will visit the research center 4 times and the will also be called once. On the day of vaccination, blood samples will be collected and a nose swab, followed by only one blood sample. During the study period, the volunteers will be asked to report information daily in a diary, starting from the day of the study vaccine administration, and for the 7 days afterwards (for a total of 8 days).

Intervention

Ad26.COV2.S

Study burden and risks

Blood draw
Drawing blood may be painful or cause some bruising. In some individuals, a blood draw can sometimes cause pallor, nausea, sweating, low heart rate, or drop in blood pressure with dizziness or fainting.

In total, we will take about 54 milliliters (mL) of blood from the volunteer. This amount does not cause any problems in adults. If the investigator thinks it is necessary for the safety of a participant, extra samples might be taken for possible additional testing. If this happens, the total amount of blood drawn will be more than the amount indicated above.

Coronavirus test
Samples for the coronavirus test will be taken from the back of the nose using swabs. Taking the samples only takes a few seconds, but can cause discomfort and can give an unpleasant feeling. When the sample is taken from the back of the nose, the volunteer may experience a stinging sensation and their eyes may become watery.

The following side effects have been observed when the Ad26.COV2.S vaccine was given to participants:

Very common side effects (affecting more than 10% of participants):
Headache, fatigue, muscle pain, nausea, injection site pain.

Common side effects (affecting 1% to 10% of participants):
Fever, chills, swelling at injection site, reddening of skin at injection site, joint pain

Uncommon side effects (affecting less than 1% of participants):
Malaise (general not feeling well), muscle weakness, pain in arm/leg, general weakness

Rare side effects with Ad26COV2.S vaccine (affecting less than 0.1% of participants):
In a phase 3 trial (study in large group of people to study effectiveness of the study vaccine) of the Ad26.CoV2.S vaccine, the following rare, serious or important conditions were reported in study participants receiving the study vaccine:
Blood clot in a deep vein, blood clot in the lungs, seizures, drooping of the face, ringing in the ear, Guillain-Barré Syndrome

Risks and possible side effects of vaccines in general
All types of injections can cause:
• Stinging, itching, arm discomfort, pain, soreness, redness, hardness, bruising and swelling where you receive the injection
• Fever and chills
• Rash
• Itching in other areas of your body
• Aches and pains
• Muscle and joint pain
• Throwing up and nausea
• Headache
• Dizziness
• Feeling very tired
• Fainting

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Participant must sign an ICF indicating that he or she understands the purpose, procedures
and potential risks and benefits of the study, and is willing to participate in the study.
2. Participant is willing and able to adhere to the prohibitions and restrictions specified in this
protocol.
3. Participant is 18 to 65 years of age, inclusive, on the day of signing the ICF.
4. Participant must be healthy, in the investigator*s clinical judgment, as confirmed by medical
history, physical examination, and vital signs performed at screening. 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-19b, except for
smoking, which is allowed (see also exclusion criterion 19). 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.

Exclusion criteria

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 within 24 hours prior to the planned study vaccination; 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)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-05-2021
Enrollment:	380
Type:	Actual

Ethics review

Approved WMO Date:	02-04-2021
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	19-05-2021
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-07-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	10-08-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-08-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	29-10-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	05-11-2021
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	EUCTR2021-001374-30-NL
CCMO	NL77273.000.21

Study results

Date completed: 08-12-2021

Results posted: 04-06-2024

First publication
22-12-2022

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

Internal documents
File