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TLP:AMBER FOR OWS USE ONLY

INFORMED CONSENT FORM

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

Study number: VAC31518COV2001

Study Sponsor

Janssen Vaccines & Prevention B.V.

Funding organizations:

- Janssen Vaccines & Prevention B.V.
- Biomedical Advanced Research and Development Authority (BARDA)

Represented by

[If appropriate, the Local Trial Manager (LTM) to insert name of local Sponsor/ Regulatory Sponsor]

[Address of local legal entity]

Study doctor [Insert Investigator name, address, and phone number]

You are kindly invited to be in a research study.

Here are a few things to know as you learn more:

- Taking part in a research study is voluntary and is not part of your regular health care.
- Our scientific question is: does the study vaccine protect people from getting COVID-19 disease?
- If you join, your participation in this study will last 14-16 months.
- If you join, you will have injections (of the study vaccine or placebo), blood draws and nasal swabs.
- If you become ill with potential COVID-19, we will ask you to provide nasal samples.
- If you take part, the most common risks are muscle aches or headaches after getting the study vaccine.
- There are other, less serious risks. We will tell you more about them later in this consent form.
- We do not know if getting the study vaccine will benefit you in any way.
- Take your time to decide – you may take an unsigned copy of this form home to read again and discuss with your other doctors, family, and friends.
- Ask the study doctor or staff your questions.

Thank you for taking the time to consider this study.

Information in this Informed Consent Form may be confidential to the Sponsor. The Sponsor is sharing this information with you for the purpose of inviting you to make an informed decision about participating in the research study. We kindly ask you to consider this sensitive information when discussing details about the research study with people other than your healthcare provider(s), family and friends.

STUDY OVERVIEW

Why is this study being done?

This study is being done to test the new experimental vaccine called Ad26.COV2.S. Doctors and scientists hope it will prevent or lessen the severity of disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). This virus causes a 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.

The new experimental vaccine being tested in this study is called Ad26.COV2.S. A vaccine helps to prevent disease 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. This study is to help determine if Ad26.COV2.S is safe for humans and if it causes an immune response that protects against COVID-19 disease.

This study will test this experimental vaccine to help doctors and scientists learn how to prevent disease caused by SARS CoV-2. The main purpose of this study is to see:

- How well Ad26.COV2.S works to prevent COVID-19 disease
- If the Ad26.COV2.S vaccine is safe
- If it causes any side effects and what they are
- How well the vaccine is tolerated by people in the study
- What the best dose of the vaccine is

Doctors and scientists will also measure:

- How long the effects of the study vaccine last
- How it acts on the body
- How the body reacts to the study vaccine (the immune response)

In this study, some participants will get a placebo instead of the Ad26.COV2.S vaccine. The placebo looks just like the Ad26.COV2.S vaccine and is given the same way, by injection (shot), in your arm muscle, but has no active vaccine in it. Using a placebo in the study allows researchers to see potential differences between the vaccine and the placebo. The placebo in this study will be sodium chloride, also known as saline (saltwater).

Throughout this document, when the words “study vaccine” are used, it can mean Ad26.COV2.S or placebo.

General Information about the study

About 550 participants will take part in this study. If you join the study, you will be in it for 14-16 months. During the study, we will collect blood and nasal swab samples. If you become sick with COVID-19- and as explained later, you cannot get COVID-19 from the vaccine- the study staff will monitor you regularly and ask you for additional nasal swab samples.

During the study, the sponsor may learn new information about the study vaccine such as risks. Your study doctor will tell you as soon as possible about any new information that might make you change your mind about being in the study, such as new risks. You may not benefit from participating in this study since we do not know if the vaccine will work. There is a small chance you may have a bad reaction to the vaccine or it may make you sicker if you get COVID-19.

You may choose not to participate and will not lose any access to medical care or other benefits otherwise available to you.

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WHAT HAPPENS DURING THE STUDY?

The study is divided into 3 parts.

1

Screening

- You must meet the requirements to be in this study and sign this informed consent form to begin.
- Screening must be completed within 28 days before you receive the first study vaccine.

2

Study Period

- The study period lasts about 5-7 months.
- You will receive the first injection on Day 1 and the second injection on Day 29, 57, or 85 depending on which vaccine group you are in. You will receive a third injection 4 months after the second injection.
- You will have 1-3 clinic visits after each injection.
- Some of the visits might be replaced with a telephone call by the study staff.
- If you stop early, you will be asked to complete an Early Exit visit.

3

Follow-up

- At the end of the Study Period, you will begin the 1-year follow-up period. This is to see how long the vaccine effects last.
- You will have 1 telephone follow visit and 1 clinic visit during this period.
- If you develop COVID-19 symptoms, you will have additional visits scheduled for testing. You will be asked to do some procedures at home.
- If you stop the study early, you will be asked to complete an Early Exit visit.

WHAT IS DONE AT THE STUDY VISITS?

Study procedures and activities

Throughout the study you may have a physical exam where we measure your height and weight, your blood pressure, heart rate, and body temperature. We will also ask you questions about your general health, medical history and medications you take.

This table describes other procedures you can expect to have during the study. Not all procedures will be done at every visit. Some procedures may not be able to be completed if you have a telemedicine visit (that is, a remote visit done by video or phone call). Some procedures may be required to be done at your home by study staff or by a home health nurse. The study doctor or study staff will discuss this with you in more detail.

Please see the Schedule of Activities tables at the end of this document to learn what procedures are done at every visit. The Schedule of Activities will vary depending on which vaccine group you are in.

Procedure	What is it?
Informed consent	The study doctor or staff will talk to you about the study and you'll decide if you want to join.
Pulse oximetry	This is measured by a small device on your finger. It is a painless test that measures the oxygen levels in your blood, and measures your heart rate
Blood draw to test for SARS-CoV-2 specific antibodies	If available, a blood test will be done at the screening visit to identify if you have been exposed to SARS-CoV-2. If the results of your blood test indicate that you have been exposed to SARS-CoV-2, it is possible that you may not be eligible for the study.
Nasal Swab Testing	At the screening visit, a cotton swab will be inserted in your nose to collect a sample for testing. You may experience some slight discomfort or tickling in the nose

	while this procedure is being done. It may also cause a nosebleed. A nasal swab kit will also be given to you so that you can collect a sample at home if you develop COVID-19-like symptoms. You will be trained by the site staff on how to use the nasal swab kit, how to store the collected sample, and when/how to return the collected sample to the study site. If necessary, your caregiver or a home nurse can assist you in collection of the swabs. The study site may arrange for supplies to be delivered to and/or samples collected from your home. For this purpose, they may need to share your contact information with a courier.
Review of risks and possible side effects of vaccines	At each visit, the study doctor/staff will ask about any side effects. All vaccines can cause side effects. Problems that are not expected may arise and they may be life-threatening. Potential risks are further outlined below in "What are the Possible Side Effects and Risks?" section. You will remain under observation by the study staff for 1 hour after each injection.
Vaccination	You will receive the vaccination with the randomly assigned study vaccine as described in the "What treatment will I receive?" within the STUDY VACCINE/OTHER MEDICATIONS section below. The place on your arm where you get the vaccine may have redness and become sore.
Diary	You will be given a diary and an explanation of how to use it. You will report information daily, starting from the day of the study vaccine, and for the 7 days afterwards (for a total of 8 daily records). Staff will show you how to note:

	• Daily symptoms, such as tiredness, headache, nausea, and muscle pain • Pain or tenderness, redness, and swelling at the site of the injection (using a ruler at home) • Your daily body temperature using a thermometer at home (you should measure your temperature at the same time each day) You must bring the diary with you to each visit.
Questionnaires	During the study period, you will be asked to complete questionnaires daily if you experience any COVID-19-like symptoms. This is done via the "daily symptom calendar". If the answer is 'Yes' for any symptom, you will need to contact the site, start to complete additional questionnaires on the development of these symptoms, and collect nasal swab samples. You may have a caregiver assist with completion of the questionnaires as needed.
Urine sample	If you are a female who could get pregnant, we will collect a urine sample from you to check for pregnancy.
Blood draw/tests	The study doctor or staff will draw blood from a vein in your arm. You may get a bruise or irritation at the place where the needle goes into your skin. Some participants may faint and, in rare cases, can get an infection. For most participants, the total amount of blood that will be drawn during the entire study is approximately 110 to 130 ml (about 8 to 9 tablespoons). Approximately 112 participants in the immune subset will have a total of 430 ml (about 1 ¾ cups) of blood drawn during the study to check the immune response. An additional 20 ml (about 1⅓ tablespoons) will be drawn from participants who develop COVID-19.

	You may be asked to repeat a blood test if there are safety or technical issues with the initial draw. • Your blood will be used: ○ For confirmation of SARS-CoV-2 infection ○ To check your immune response to the study vaccine The study doctor or staff will discuss with you the test results that are medically important.
Sample collection for scientific/genetic research	Any of your blood samples could be used for scientific and limited genetic research as described in the "Samples Collected for Scientific/Genetic Research" section below. You will be informed if testing on your samples for this study will change.
Review of concomitant medications	You will talk with the study doctor or staff about any other medications you take including prescription medicines, over the counter medications, supplements, vitamins, or herbal products.
Phone calls or telemedicine visits	During the study, the study staff will contact you regularly by telephone or other means of communication to remind you of what you need to do in case you are experiencing COVID-19 symptoms. It might also be possible that certain on-site study visits will be replaced by telephone calls or home visits by study staff.

Study rules

To participate in the study, you must follow this list of things to do and not do:

Overall study rules	
Do	**Do not**
• Give correct information about your health history and health condition • Tell the study doctor and staff about any health problems you have during the study. Note: you should contact the study staff as soon as you start experiencing COVID-19-like symptoms. • Talk to your study doctor before getting any other licensed vaccines (such as flu vaccine). • Complete the vaccine diary and questionnaires and bring to all visits • Provide all required samples, e.g. nasal swabs and blood draws • Come to all study visits • Agree and be able to be contacted by the study staff on a regular basis	• Do not take part in any other medical research studies (including other COVID-19 vaccine studies) • Do not get pregnant or cause someone else to become pregnant
Medicines	
Do	**Do not**
• Tell the study doctor and staff about any new medicine or drug you take during the study, including over-the-counter drugs (for example, to prevent or treat side effects of the study vaccine). Also tell the study doctor and staff about any changes to your medicines or drugs.	

Other	
Do	**Do not**
• Bring the "Patient Instructions for Hospitalization" letter with you to the hospital if you require care at a hospital for any reason.	

STUDY VACCINE/OTHER MEDICATIONS

What is the study vaccine?

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 has been weakened so it cannot cause an infection.

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 small bits specific to SARS-CoV-2. Our bodies recognize these proteins and make an immune response against them. This immune response is our body's way of fighting the infection. You cannot contract COVID-19 from the study vaccine.

Ad26.COV2.S is experimental, which means it is not approved for use by any Regulatory Authority in any country. Therefore, it can only be used in a research study that is approved by the sponsor, such as this one.

What treatment will I receive?

There are 10 treatment groups in this study. Each study participant will be assigned to one group.

Not everyone in the study will get Ad26.COV2.S. You will either get Ad26.COV2.S or placebo. You will randomly (by chance) be put into the Ad26.COV2.S or placebo vaccine group. You have an 86% chance (475 out of the 550 participants) of getting the Ad26.COV2.S vaccine.

During the study, neither you nor the study staff will know which vaccine group you're in. In a medical emergency, the study doctor and staff can quickly find out which vaccine group you're in.

How is the study vaccine given?

The study vaccine is given by injection. A needle is put into the muscle of your upper arm. You will receive the study vaccine three times during the study.

You must remain at the study site for observation for one hour after receiving the study vaccine.

What other treatments are there outside of this study?

Do not remove this guidance box from the Master ICF.

ICF Author to add alternative treatments in consultation with SRP/SRS and other study representatives, as applicable. If there are no alternative treatments, this must be stated.

<LTM to modify list based on locally available treatments.>

There are currently no approved vaccines for COVID-19. However, there may be other clinical studies testing different potential vaccines against COVID-19. The study doctor will explain to you the benefits and risks of these other treatments.

What about my current medicines?

You must tell the study doctor and staff about all your prescription and over-the-counter medicines. This includes vitamins and herbs.

You may continue to take your medication(s) while you are in this study.

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING?

Risks

The Ad26.COV2.S vaccine has been studied in the test tube and in animals with no vaccine-related adverse effects observed.

Vaccines similar to Ad26.COV2.S (that is, Ad26-based vaccines) have been given to participants in studies designed to prevent RSV (Respiratory Syncytial Virus), HIV (Human Immunodeficiency Virus), Ebola/filovirus, Zika virus, HPV (Human Papillomavirus) and malaria. As of 04 September 2020, approximately 114,000 participants were vaccinated with Ad26-based vaccine in ongoing studies, including an ongoing government-led immunization campaign in Rwanda (UMURINZI Ebola Vaccine Program campaign).. Pain, tenderness and redness at the injection site, headache, chills, joint pain,

muscle pain, tiredness, generally not feeling well, nausea and fever have been seen with these study vaccines. These reactions usually start within 1 to 2 days after the injection and most of the reactions get better within 1 to 3 days.

As of 10 September 2020, a single injection of Ad26.COV2.S has been administered to 805 human participants, aged 18 and older. Following administration of Ad26.COV2.S, fever, fatigue, muscle aches and headache appear to be more common in younger adults and can be severe. For this reason, we recommend you take a fever reducer or pain reliever if symptoms appear after receiving the vaccination, or upon your study doctor's recommendation. Please tell the study staff if you take anything.

In a Phase 3 trial of Ad26.CoV2. S vaccine, one study participant developed a serious condition, a clot in a blood vessel in the brain that then resulted in bleeding into the brain. Symptoms included severe and persistent headache, confusion, blurred vision, and seizures. There are many possible factors that could have caused the event. After a thorough evaluation, no clear cause has been identified. At this time, it is unknown if the vaccine caused this condition, however, the possibility that the vaccine may have contributed to this event cannot be excluded.

If you develop symptoms like severe and/or persistent headache, confusion or blurred vision, you should promptly notify your healthcare provider and/or study team.

Some vaccines may cause a more severe course of disease when you are vaccinated against a disease and then become infected by that disease germ. This is called vaccine-enhanced disease and it has been described during animal testing for some vaccines against other coronavirus infections such as SARS (Severe Acute Respiratory Syndrome) and MERS (Middle East Respiratory Syndrome). However, studies in human volunteers with vaccines using similar technology to Ad26.COV2.S have produced responses that are not associated with vaccine-enhanced disease. Nevertheless, the risk of a more severe course of SARS-CoV-2 infection cannot be absolutely ruled out with the vaccine tested in this study. Because of this, all participants in this study will be monitored for vaccine-enhanced disease throughout the study. We will do this by taking nasal swabs in participants suspected of having SARS-CoV-2 infection. Study participants with a positive test result will be followed until the signs and symptoms have been resolved. These procedures will allow us to recognize and intervene early in the course of disease. Early recognition and intervention will reduce the risk of a bad outcome if enhanced disease should occur.

All vaccines can cause side effects. Problems that are not expected may happen and these may be life-threatening. If you have any side effects or problems during this study, please tell your study doctor right away.

There may be risks associated with Ad26.COV2.S that we don't know about yet. If we learn new information about the study vaccine and risks associated with it, we will tell you.

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

These side effects usually last 2 to 3 days.

Rarely, people may have more severe side effects that limit their normal activities or make them go to the doctor.

Allergic reactions

You could have an allergic reaction to a vaccine, including a rash, hives, or difficulty breathing. Some allergic reactions can be life-threatening. The study staff will watch you for one hour after each injection.

Risk of Testing Positive for SARS-CoV-2 Antibodies

If you receive the AD26.COV2.S vaccine, your body may have an immune response to the specific coronavirus protein that is part of the vaccine. This immune response will not affect any results of COVID-19 tests whether taken as part of the study or outside of the study, that are obtained from a swab of your nose or from your throat as these tests tell you if you currently have COVID-19 virus in your body. Some tests, however, are done to check if you have previously been infected with COVID-19—these tests check for antibodies. These antibody test results might be positive if you received the AD26.COV2.S vaccine, even if you were never truly infected with the virus. For this reason, we

recommend that you speak with study staff if you need to get tested for COVID-19 outside of this study. The study staff will provide you with additional information and help you get the right test.

If you become pregnant during or after the study and have antibodies in response to the vaccine, we don't know if the antibodies can be passed to your baby. We do know that antibodies from other vaccines, like tetanus vaccine, do get passed to the baby. For most babies, antibodies passed from the mother last for about six months.

COMMON QUESTIONS ABOUT JOINING THE STUDY

Will I be paid?

Do not remove this guidance box from the Master ICF.

Any statements regarding compensation or reimbursement must be consistent with all study-related documents (e.g., the protocol, CTA, patient recruitment advertising materials or documents submitted by the investigational sites for review and approval). Any applicable company policies (e.g., Healthcare Compliance [HCC] policies) which cover these should be aligned.

You will receive reasonable reimbursement for study related costs (ex. travel, parking costs).

Who pays for the study vaccine and tests?

Do not remove this guidance box from the Master or Country ICFs.

The following is a requirement per Declaration of Helsinki: A placeholder for information regarding potential conflicts of interest is included in this section to be completed by the site (investigator). Include financial relationships or interests associated with the study e.g., the source of funding and funding arrangements for the conduct and review of the study or information about a financial arrangement or interest of an institution or an investigator such as stock in the sponsor or patent on the investigational product. State if the investigator has no financial relationships or interests associated with the study.

There are no costs to you to be in the study. The sponsor will pay for the study vaccine and tests that are part of the study.

The sponsor will not pay for doctor visits, treatments, or tests that are not part of this study. The sponsor will not pay for [insert co-medications or other treatments described in the protocol and ICF that will not be paid for by the sponsor].

This means that you, your insurance company, or your government health plan are responsible for paying for [insert co-medications, other treatments, or study vaccines (if applicable) that will not be paid for by the sponsor].

[LTM/SM TO INCLUDE A STATEMENT ABOUT FINANCIAL ARRANGEMENTS / CONFLICT OF INTEREST OR LACK THEREOF.]

Can the study staff remove me from the study?

Yes, the study doctor/staff and the study sponsor have the right to remove you from the study at any time, with or without your agreement. Removal from the study may happen if:

- It is in your best medical interest to stop
- You do not follow the study staff's instructions
- The study is canceled
- You no longer meet the eligibility criteria

The study doctor/staff will discuss with you the reasons for removing you from the study, other treatment or research options, and plans to follow up with you for side effects.

Can I change my mind about participating?

Yes, you can agree to be in the study now and change your mind **at any time and for any reason**. You can withdraw from the study and your decision will not change your regular care from your doctors.

Please talk to your study doctor first before deciding to change your participation.

What happens if I stop the study early?

If you stop the study early, the study doctor or staff will conduct an Early Exit visit with you as soon as possible. This is to check your health. This information will be added to your study record. If you do not want the study doctor to continue monitoring your health after you stop taking the study vaccine, you will be asked to indicate this by informing the study doctor. However, it is recommended that you continue to have the study doctor follow you for safety for a period of time.

If the study doctor or staff is unable to contact you by conventional means (e.g., clinic/practice visit, telephone, e-mail, fax, or certified mail), he/she may also contact you by reaching out to your emergency contact or by locator agencies and public records, as permitted by local regulations to find out about your health status. By signing this consent form, you agree that this information can be obtained and added to your study record.

If you have side effects from the study vaccine or study procedures after you stop the study early, the study doctor or staff may contact your other doctors who you see regularly to get information about your side effects. By signing this consent form, you agree that this information can be obtained and added to your study record.

[LTM TO INCLUDE A STATEMENT OUTLINING MEASURES TAKEN TO IDENTIFY LOSS TO FOLLOW-UP PATIENTS AS ALLOWED PER LOCAL REGULATIONS].

If you stop the study early and withdraw your consent at any time, you agree to allow the use of information collected about you for the purpose of the study up to the point of your consent withdrawal. The Sponsor will continue to collect information from you as described in other sections of this Informed Consent Form (see "Samples Collected for Scientific/Genetic Research," "Samples Used for Future Research," and "What happens if I stop the study early?"). The Sponsor will not collect any new information from you for any parts of the study from which you have withdrawn.

Can I take the study vaccine after the study is over?

This section must align with Post Trial Responsibilities (PTR) as outlined in the protocol. Adapt the text depending if PTR are provided via Extension trials or via Post Trial independent requests.

<LTM MUST ENSURE THAT THE PTR DECISION ALIGNS WITH LOCAL REGULATIONS>

After you complete the trial, you will no longer receive the study vaccine [LTM TO MOFIDY BASED ON LOCAL REQUIREMENTS]. After the trial, a plan will be developed in accordance with local and national regulatory authorities to determine if and when it is recommended that those participants who received placebo vaccine may be vaccinated with the Ad26.COV2.S vaccine. Neither you nor your doctor will know which vaccine you were assigned until after the end of the study. As a result, placebo participants may not receive Ad26.COV2.S for at least 15 months after initial vaccination. Your study doctor or staff will discuss your future medical care options with you.

What are the benefits of joining this study?

There is no direct medical benefit to you for participation in this clinical study. Your participation may help future patients and may serve to further research of COVID-19 disease.

What about my regular doctors?

The study doctor or staff may let your regular doctors know that you are in this study and may report any side effects that you experience from your participation in this study. It is important for your other doctors to know that you may be taking an experimental vaccine.

WHAT IF SOMETHING GOES WRONG?

SUBJECT INJURY: Do not remove this guidance box from the Master ICF.

The LTM will complete this section. It must include the country-specific injury language required by local/legal regulations. The text in this section of the site-specific ICF must be consistent with the clinical trial agreement.

CAUTIONS

Birth control and pregnancy during the study

Animal studies have shown that Janssen's licensed Ad26-based vaccine against Ebola did not raise concerns in preclinical reproductive toxicity studies. These are studies in pregnant animals that received the vaccine, and the delivered animal babies. Therefore, ongoing studies with the Ebola vaccine allow pregnant women and women planning to become pregnant to receive that vaccine. However, these studies are not yet available for Ad26.COV.S. For this reason, in this study, we will not enroll pregnant women, or those who aim to get pregnant within 3 months of receiving the study vaccine. The appropriate animal studies are currently underway.

Female Participants Who Cannot Get Pregnant

If you are postmenopausal for at least one year or have had a total hysterectomy (surgical removal of the womb) or bilateral tubal ligation/clip (surgical sterilization) or surgical removal of both ovaries, you cannot get pregnant. Therefore, the section about contraceptive use does not apply to you.

Female Participants Who Can Get Pregnant

If you are female and can get pregnant (meaning that you are neither post-menopausal for one year nor surgically sterile) and sexually active, you must avoid getting pregnant in order to take part in this study. You will be required to agree to use an approved method of birth control (as described below) beginning 28 days prior to the first study vaccination and continuing for 3 months after the administration of last study vaccination. In addition, you will need to have a negative pregnancy test before each vaccination.

Birth control methods that can be used while in this study include:

- Hormonal contraception

- Intrauterine devices (IUD)
- Intrauterine hormone-releasing systems
- Vasectomized partner (the vasectomized partner should be your sole partner)
- Abstinence (defined as refraining from heterosexual intercourse from signing the informed consent until at least 3 months following the last study vaccination)

Please talk to the study staff about specific questions concerning acceptable birth control methods. He/she must approve the method you use before you can enter the study.

If you are a female who can get pregnant, you must agree to have a urine β-hCG pregnancy test at screening and immediately prior to each study vaccine administration to confirm that you are not pregnant.

If you suspect that you have become pregnant during the study, you must notify your study doctor immediately. If you become pregnant during the study, you will not receive any further vaccinations. However, you may continue in other study procedures (you may have blood drawn for safety and immune response testing), if the investigator decides it is safe for you and your unborn child. The study doctor will collect information about your pregnancy and the health of your baby. If you do not wish to be followed, you can withdraw your consent at any time by informing your doctor.

Male Participants

If your partner becomes pregnant during the study, you should tell the study doctor immediately. Your partner will be asked for permission to allow the study doctor to follow up and collect information about her pregnancy and the health of the baby. It is entirely voluntary. Your partner does not have to provide any information.

SAMPLES COLLECTED FOR SCIENTIFIC/GENETIC RESEARCH

What happens to the samples collected from me?

The sponsor may use any of your samples collected during this study to:

- Understand how Ad26.COV2.S vaccine works, or why it may cause side effects
- To better understand COVID-19 disease
- Understand why people may respond differently to the study vaccine

- To better understand the vaccines made from adenoviruses
- To develop tests for Ad26.COV2.S vaccine and SARS-CoV-2 infections.

Researchers may use your samples for genetic testing. Genetic research is the study of DNA and RNA. Differences in genes may explain why some people respond to some medications and others do not. It may also explain why some people get some diseases and others do not.

[LTM TO MODIFY BASED ON LOCAL REQUIREMENTS – ESCALATE TO BIOMARKER REPRESENTATIVE IF THERE ARE CHANGES:] The results of tests done on these samples are only for scientific research. They will not be used for your medical care. They will not be used to make a diagnosis about your health. Therefore, these results will not be given to you or the study doctor/staff.

To protect your privacy, your samples will be labeled with the study number and participant number. No personal identifiers are used (such as name, initials, social security number). The scientists doing the research will not know your identity.

Your samples may be sent to the sponsor and other members of the Johnson & Johnson group of companies and to contractors working for them. Your samples may also be shared with other researchers. Your samples will not be sold. Researchers working with the Sponsor are not allowed to share samples with anyone who is not authorized by the Sponsor.

You will not be paid for any use of your samples, results, or inventions made from research on them. You are providing your samples for use by the sponsor. The sponsor (and research partners, where applicable) will own the use of the results, treatments, or inventions that can be made from this research.

Your collected samples will continue to be analyzed as described in this form unless you specifically ask for your samples to be destroyed. This is to protect the quality of the study.

Samples Used for Future Research

Future Research Testing: Any samples leftover after they are used for the main study will be stored for future use (up to 15 years or as defined by local regulations). Testing will depend on the available technology at the time of testing. Additionally, your samples could be used for future COVID-19 (or other respiratory viral diseases) vaccine research.

You may opt out of future use of your samples and can withdraw your consent at any time during or after the study by notifying your study doctor. If you withdraw consent for future use of your samples, your samples will be destroyed after they are no longer required for the main study. This will not affect your access to the care, medicine, and equipment you would otherwise be getting.

This can be done at any time and for any reason. You will need to do this before [#] years since the study doctor/staff will discard the medical records that link your name to your study number in [insert # based on local regulations] years.

The sponsor plans to keep the samples securely in [insert name of [a] facility[ies] in [insert geographical location]. The samples may be re-located at any time by the sponsor.

HOW IS MY PRIVACY PROTECTED?

Privacy Language: Do not remove this guidance box from Master ICF.

This section includes boilerplate privacy language only for Global Master ICF.

<LTM MUST INSERT THE LEGAL AND PRIVACY WORDING THAT IS THE APPROVED COUNTRY-SPECIFIC TEXT REQUIRED BY LOCAL REGULATIONS **THROUGHOUT** THIS SECTION OF THE ICF. SAMPLE LANGUAGE AND KEY ELEMENTS ARE PROVIDED IN THE COUNTRY ICF LANGUAGE SUMMARY.>

<LTM/SM: THE LANGUAGE IN THE SITE-SPECIFIC ICF MUST BE CONSISTENT WITH THE SPECIFIC CLINICAL TRIAL AGREEMENT.>

NOTE: THE TEXT IN THIS SECTON DOES NOT COVER ALL INFORMATION EXPECTED TO ADDRESS DATA PROTECTION AND PRIVACY. For example:

- The statement that the Clinical Trial will be available on www.clinicaltrials.gov is included in another section of the ICF).
- Information about withdrawal, including the requirement (if applicable) to consult public records to find out the health status of the participant is including in section "What happens if I stop the study early?"

Refer to Job Aid: Escalation of Requested ICF Changes in case of requested changes to privacy language.

The Study Staff and the Sponsor will manage your personal data (information about you) in compliance with [insert reference to applicable law on data protection and privacy] as described in this consent form.

What personal data will the study staff collect?

If you join this study, the study doctor/staff will collect and use your personal data to do the research. This personal data may include, among other items, your name, address, date of birth, and health data (information about your health). Health data includes past medical records and data collected during this study, including data collected when analyzing your biological samples as described in "What is Done at the Study Visits?"

Sensitive data such as racial or ethnic origin will also be collected, as it is necessary for the evaluation of the study results.

Who will have access to your personal data?

Your personal data may be stored in paper files and electronic databases which have limited access. The study doctor and staff will have access to these paper files and databases. Other people may also need direct access to this information to ensure that the research study is being conducted properly, in accordance with laws and ethical requirements.

Monitor(s), auditor(s), IRB/IEC, and regulatory authorities will be granted direct access to your original medical records for verification of clinical study procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing this informed consent form, you authorize such access.

Records identifying you will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, your identity will remain confidential.

Remote access to your records at the study site

Representatives of the sponsor (i.e., auditors) may use an electronic tool to access your personal data remotely. This electronic tool provides a secure electronic gateway between the study doctor and staff's computer system and the computer of the representatives of the sponsor, who may be located outside of your country of residence. This minimizes the risk that anyone else might be able to access the information.

How will your personal data be protected?

Your personal data will be labeled with the study number and your subject number ("Your Coded Data") before it is reported to the sponsor. No direct personal identifiers such as your name, initials, date of birth, or social security number are included in Your Coded Data.

How will Your Coded Data be used?

Your Coded Data is needed for the sponsor to learn about Ad26.COV2.S, get permission to introduce and keep it on the market, monitor its safety and get it covered by health insurances and health service providers. Therefore, they will be used as planned in this study as well as within related research activities in order to:

- understand how Ad26.COV2.S and similar vaccines work in the body;
- better understand COVID-19 and associated health problems;
- develop diagnostic tests;
- learn from past studies to plan new studies or improve scientific analysis methods;
- publish research results in scientific journals or use them for educational purposes.

How will Your Coded Data be shared and transferred?

The sponsor may share Your Coded Data with its affiliates, regulatory authorities, authorized service providers and, with select investigators and scientists conducting scientific research, which is compatible with research related to this study including statistical purposes. Your Coded Data may also be shared with scientific journals so the study results can be reviewed by independent scientists and to ensure the accuracy of results. Your identity will not be revealed in any of these cases.

The Sponsor will protect Your Coded Data as far as the law allows and will keep and supervise the information collected about you only for as long as needed.

Sharing of your anonymized data

Anonymized means your data and samples will be stripped of your participant number as well as of any other information that could identify you. This anonymized data and samples may be shared only for scientific research as allowed by law.

How long will my personal data be stored?

Records containing your personal data will be retained at the study site for a period of [insert retention period as per local requirements]. In addition, the Sponsor will retain Your Coded Data for time periods as allowed per applicable laws for the identified use.

What rights do I have concerning my personal data?

If you would like to review, correct, delete personal data, or make other requests concerning your personal data in accordance with the laws in your country, you should contact your Study Doctor at [insert contact details].

Please note that you may not be able to review some of the data until after the end of the study, and a request to delete your personal data cannot be fulfilled where regulations and laws that apply to clinical research require your personal data to be retained.

You can request your study doctor to forward any questions, concerns or complaints you may have to the Sponsor of this study or its representative.

WHAT HAPPENS AFTER THE STUDY?

PLS Language: Do not remove this guidance box from Master ICF.

Plain Language Summary (or "PLS") language is to be included verbatim if study qualifies per EU Clinical Trial Regulation and/or voluntary adoption.

<LTM MUST NOTIFY CTM IN THE EVENT OF ANY LOCAL REQUESTED CHANGES (INCLUDING REMOVAL) TO THE PLS LANGUAGE>

After all study participants have completed the study (which may be some time after you have completed your participation in the Study), the Sponsor will analyze the data and offer you a summary of the study results that are understandable to the general public. The summary will not include individual results or information that can identify you or any other study participant. The summary may be made available to you through a study participant web portal which you can choose to access or through certain local and/or national websites.

GENERAL STUDY INFORMATION

Who do I contact for information?

If you have any questions about the study, please contact:

[Insert appropriate study site personnel name, phone number, and title]

If you feel that this study has caused you any harm, please contact:

[Insert Investigator name, phone number, and title]

If you have any questions about your rights as a research participant, please contact the study doctor/staff or:

[Insert IRB or IEC name and phone number]

Study information

Study title: 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

Study number: VAC31518COV2001

A description of this clinical trial will be available on www.clinicaltrials.gov/ as required by U.S. law. In addition, it will also be available on www.clinicaltrialsregister.eu and [LTM to insert other local registries as applicable]. This website will not include information that can identify you. At most, the website will include a summary of the study results. You can search this website at any time.

[INCLUDE IF REQUIRED BY LOCAL IRB/IEC:] An independent ethics committee or institutional review board has approved this study.

YOUR AGREEMENT TO PARTICIPATE

If you consent, please read and then sign below.

- I have read and understood this information.
- This study has been explained to me.
- All my questions about the study, the (Ad26.COV2.S) experimental vaccine, and possible risks and side effects have been answered to my satisfaction.
- I give permission for my doctors, other health professionals, hospitals, or labs to release information to [institution/clinic (name) /clinical investigator (name)] about my health for the purposes of this study. I understand this information will remain confidential.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study.
- I understand that I will be given a signed copy of this document to keep.

Based on this information, I volunteer to take part in this study.

- I have been informed that the study doctor/staff may inform my other doctors, if any, about my participation in this study, and I agree to this. (You may still be in this study even if you do not agree to this.)

  Check Yes, No, or Not applicable:

  Yes ☐ No ☐ Not applicable, I have no other doctors ☐

- I agree to the use of my blood for future scientific research as described in section "Samples Collected for Scientific/Genetic Research," in addition to the testing required for this study.

  Check Yes or No:

  Yes ☐ No ☐

You will receive a copy of this signed Informed Consent Form.

[INCLUDE AS APPROPRIATE:] [Collect the time (HH:MM) if there is a time sensitivity (e.g., time-sensitive signatures obtained during a medical emergency)].

[NOTE: THE USE OF ELECTRONIC, INCLUDING DIGITAL, SIGNATURES MUST BE IN COMPLIANCE WITH THE APPLICABLE LOCAL REGULATIONS]

_____
Printed name of participant in full

_____
Signature of participant Date (dd/MON/yyyy)

Printed name of person obtaining consent

Signature of person obtaining consent Date (dd/MON/yyyy)

[THE FOLLOWING INVESTIGATOR SIGNATURE MAY BE DELETED, IF NOT APPLICABLE:]

Printed name of investigator if different from the person obtaining consent

Signature of investigator if different from the person obtaining consent Date (dd/MON/yyyy)

[INCLUDE THE FOLLOWING OPTIONAL SIGNATURES AS REQUIRED BY NATIONAL/LOCAL REGULATIONS FOR THE CONSENT OF MINORS, ADOLESCENTS, OR PARTICIPANTS WHO CANNOT CONSENT FOR THEMSELVES (E.G., REQUIRE A LEGALLY ACCEPTABLE REPRESENTATIVE:]

Legally Designated Representative Signature, if applicable:

Printed name of Legally Designated representative, in full

Signature of Legally Designated Representative Date (dd/MON/yyyy)

Relationship of Legally Designated Representative to the participant

Impartial Witness Statement [THE IMPARTIAL WITNESS SIGNATURE MUST BE KEPT IN THE MAIN ICF UNLESS THE PROTOCOL REQUIRES PARTICIPANTS MUST BE ABLE TO READ AND WRITE.]

At least one **impartial** witness is mandatory when the participant or participant's legally acceptable representative is unable to read or write. An **impartial** witness must be present during the entire informed consent discussion.

I confirm that the information in the consent form was accurately explained to, and apparently understood by, the participant and/or the participant's legally acceptable representative, and that consent was freely given by the participant and/or the participant's legally acceptable representative.

Printed name of Impartial Witness, in full

Signature of Impartial Witness Date (dd/MON/yyyy)

Table 1: Groups 1 to 6

Visit Number	1	2	3	4	5	6	7	8	9	10	11	12	13☎	14	Early Exit
Visit Timing	**Screening**	**Vac 1 (Day 1)**	**Vac 1 +7d**	**Vac 1 + 14d**	**Vac 1 + 28d**	**Vac 2 (Day 57)**	**Vac 2 + 7d**	**Vac 2 + 14d**	**Vac 2 + 28d**	**Vac 3 (Day 169)**	**Vac 3 + 7d**	**Vac 3 + 28d**	**Vac 3 + 6mo.**	**Vac 2 + 12mo.**	
Informed Consent	●														
Medical History, Review pre-study medication	●														
Physical Examination*, incl. height and weight	●														
Pulse oximetry and distribution of pulse oximeter		●													
Vital signs incl. body temperature	●	●	●	●	●	●	●	●	●	●	●	●		●	●

Visit Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13☎**	**14**	**Early Exit**
Visit Timing	**Screening**	**Vac 1 (Day 1)**	**Vac 1 +7d**	**Vac 1 + 14d**	**Vac 1 + 28d**	**Vac 2 (Day 57)**	**Vac 2 + 7d**	**Vac 2 + 14d**	**Vac 2 + 28d**	**Vac 3 (Day 169)**	**Vac 3 + 7d**	**Vac 3 + 28d**	**Vac 3 + 6mo.**	**Vac 2 + 12mo.**	
Blood draw for serology test (antibodies), if available	•	•													
Nasal swab testing	•	•													
Nasal swab kit training and distribution		•													
Vaccination		•				•				•					
Diary Distribution (including ruler and thermometer)		•				•				•					
Complete vaccine diary		Vac day + 7 days				Vac day + 7 days				Vac day + 7 days					
Review of diary			•				•				•				

Visit Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13☎**	**14**	**Early Exit**
Visit Timing	**Screening**	**Vac 1 (Day 1)**	**Vac 1 +7d**	**Vac 1 + 14d**	**Vac 1 + 28d**	**Vac 2 (Day 57)**	**Vac 2 + 7d**	**Vac 2 + 14d**	**Vac 2 + 28d**	**Vac 3 (Day 169)**	**Vac 3 + 7d**	**Vac 3 + 28d**	**Vac 3 + 6mo.**	**Vac 2 + 12mo.**	
Urine pregnancy test (if applicable)	●	●				●				●					
Blood sample		●		●	●	●	●	●	●	●	●	●		●	●
Review side effects, Review for COVID-19-like signs and symptoms (daily questionnaire)										Continuous					
Review concomitant medications										Continuous					

***Full exam at screening then symptom-directed physical exam at other visits, if necessary**

☎Phone call from study staff or doctor

VAC = vaccination; d = day; mo. = month; Incl. = including

Table 2: Groups 7 and 8

Visit Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11☎**	**12**	**Early Exit**
Visit Timing	**Screening**	**Vac 1 (Day 1)**	**Vac 1 +7d**	**Vac 2 (Day 29)**	**Vac 2 + 7d**	**Vac 2 + 14d**	**Vac 2 + 28d**	**Vac 3 (Day 148)**	**Vac 3 + 7d**	**Vac 3 + 28d**	**Vac 3 + 6mo.**	**Vac 2 +12mo.**	
Informed Consent	●												
Medical History, Review pre-study medication	●												
Physical Examination*, incl. height and weight	●												
Pulse oximetry and distribution of pulse oximeter		●											
Vital signs incl. body temperature	●	●	●	●	●	●	●	●	●	●		●	●
Blood draw for serology test (antibodies), if available	●	●											
Nasal swab testing	●	●											
Nasal swab kit training and distribution		●											
Vaccination		●		●				●					

Visit Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11☎**	**12**	**Early Exit**
Visit Timing	**Screening**	**Vac 1 (Day 1)**	**Vac 1 +7d**	**Vac 2 (Day 29)**	**Vac 2 + 7d**	**Vac 2 + 14d**	**Vac 2 + 28d**	**Vac 3 (Day 148)**	**Vac 3 + 7d**	**Vac 3 + 28d**	**Vac 3 + 6mo.**	**Vac 2 +12mo.**	
Diary Distribution (including ruler and thermometer)		●		●				●					
Complete vaccine diary		Vac day + 7 days		Vac day + 7 days				Vac day + 7 days					
Review of diary			●		●				●				
Urine pregnancy test (if applicable)	●	●		●				●					
Blood sample		●		●	●	●	●	●	●	●		●	●
Review side effects, Review for COVID-19-like signs and symptoms (daily questionnaire)		Continuous											
Review concomitant medications		Continuous											

***Full exam at screening then symptom-directed physical exam at other visits, if necessary**

☎Phone call from study staff or doctor

VAC = vaccination; d = day; mo. = month; Incl. = including

Table 3: Groups 9 and 10

Visit Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**112☎**	**13**	**Early Exit**
Visit Timing	**Screening**	**Vac 1 (Day 1)**	**Vac 1 +7d**	**Vac 1 + 28d**	**Vac 2 (Day 85)**	**Vac 2 + 7d**	**Vac 2 + 14d**	**Vac 2 + 28d**	**Vac 3 (Day 204)**	**Vac 3 + 7d**	**Vac 3 + 28d**	**Vac 3 +6mo.**	**Vac 2 +12mo.**	
Informed Consent	●													
Medical History, Review pre-study medication	●													
Physical Examination*, incl. height and weight	●													
Pulse oximetry and distribution of pulse oximeter		●												
Vital signs incl. body temperature	●	●	●	●	●	●	●	●	●	●	●		●	●
Blood draw for serology test (antibodies), if available	●	●												
Nasal swab testing	●	●												

Visit Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**112☎**	**13**	**Early Exit**
Visit Timing	**Screening**	**Vac 1 (Day 1)**	**Vac 1 +7d**	**Vac 1 + 28d**	**Vac 2 (Day 85)**	**Vac 2 + 7d**	**Vac 2 + 14d**	**Vac 2 + 28d**	**Vac 3 (Day 204)**	**Vac 3 + 7d**	**Vac 3 + 28d**	**Vac 3 +6mo.**	**Vac 2 +12mo.**	
Nasal swab kit training and distribution		●												
Vaccination		●			●				●					
Diary Distribution (including ruler and thermometer)		●			●				●					
Complete vaccine diary		Vac day + 7d			Vac day + 7d				Vac day + 7day					
Review of diary			●			●				●				
Urine pregnancy test (if applicable)	●	●			●				●					
Blood sample		●			●	●	●	●	●	●	●		●	●
Review side effects, Review for COVID-19-like signs and		Continuous												

Visit Number	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**112☎**	**13**	**Early Exit**
Visit Timing	**Screening**	**Vac 1 (Day 1)**	**Vac 1 +7d**	**Vac 1 + 28d**	**Vac 2 (Day 85)**	**Vac 2 + 7d**	**Vac 2 + 14d**	**Vac 2 + 28d**	**Vac 3 (Day 204)**	**Vac 3 + 7d**	**Vac 3 + 28d**	**Vac 3 +6mo.**	**Vac 2 +12mo.**	
symptoms (daily questionnaire)														
Review concomitant medications		Continuous												

***Full exam at screening then symptom-directed physical exam at other visits, if necessary**

☎Phone call from study staff or doctor

VAC = vaccination; d = day; mo. = month; Incl. = including

Table 4: Shows what happens each day for participants who experience COVID-19-like symptoms

Beginning of signs and symptoms	**COVID-19 Day 1**	**COVID-19 Days 1-4**	**COVID-19 Days 3-8**	**COVID-19 Day 29**	**Until symptoms are resolved**
Contact study site as soon as you have any signs or symptoms of COVID-19	●				
Collect nasal swab at home		●	●		
Physical examination*				●	
Vital signs including body temperature				●	
Blood sample			●	●	
Pulse oximetry by site staff			●		
Take body temperature and record the highest temperature each day		Daily			
Complete questionnaire: Symptoms of Infection with Coronavirus-19 (SIC).		Daily			
Pulse oximetry at home		3 times a day			
Study site staff will contact you	Weekly or more frequently				

***Symptom-directed physical exam, if necessary**