PARTICIPANT INFORMATION SHEET: COV008

A Phase I study to determine safety, tolerability and immunogenicity of intranasal administration of the COVID vaccine ChAdOx1 nCOV-19 in healthy UK adults

IMPORTANT: If you develop a fever, cough, shortness of breath, loss of sense of smell or taste, or become unwell then you must contact the study office on 01865 617799 for advice before attending any visit.

Please note: this number is staffed in office hours only – a different number will be given to vaccinated volunteers to allow them to contact the clinical team at any time.

Participation could really make a difference during the public health emergency.

We would like to invite you to take part in our COVID-19 vaccine study. Before you make a decision, it is important that you take the time to understand why we are doing this research and what it involves. Please read the following information carefully, and consider discussing it with friends and relatives.

What is the purpose of this research study?

The purpose of this study is to investigate an alternative way to give the ChAdOx1 nCoV-19 vaccine (also known as the Oxford/ AstraZeneca vaccine). Currently the vaccine is given by intramuscular injection, normally in the upper arm. In this trial, the vaccine will be given as a spray into the nose (intranasally).

COVID-19 was declared a pandemic by the WHO on 11th March 2020. Millions of deaths have been reported since, despite unprecedented containment efforts.

COVID-19 is caused by the SARS-CoV-2 virus. This is part of the Coronavirus family, which cause respiratory infections ranging from the common cold to more severe diseases. Common symptoms of COVID-19 include fever, tiredness, and dry cough. About 1 in 6 people who get COVID-19 become seriously ill.

A large proportion of people infected have mild symptoms, or none at all. These people will recover without needing medical treatment, but are still able to pass the virus on to other people. It is becoming clear that this route of transmission is particularly important in the spread of the virus.

ChAdOx1 nCoV-19 is one of the COVID-19 vaccines currently approved for emergency use in the UK. Though these vaccines protect against serious illness, they do not completely prevent people without symptoms from passing the virus on.

Studies suggest that intranasal vaccination may reduce the amount of virus in the nose of infected people more effectively than standard vaccination. This added effect could reduce the risk of people passing the virus on, as well as protecting them from serious infection. It would also provide a method of vaccination that does not require a needle, which some people may prefer.

This study will enable us to assess the safety of intranasal ChAdOx1 nCoV-19 vaccine, as well as how well participants' immune systems respond to the vaccine.

Summary of the study

In total this study will enrol up to 54 adults.

- Participants will receive at least one intranasal dose of ChAdOx1 nCoV-19
- Half the participants will be randomly allocated to receive a second (booster) dose of the vaccine
- Following both vaccinations there will be appointments to:
    - Check for any problems
    - Monitor your health
    - Study immune responses to the vaccine.
- There will be an electronic diary to complete for up to 28 days following vaccination
- The study will take approximately 4 months complete, involving a total of 7-10 visits, depending on which group you are in.

What is the vaccine we are testing?

The vaccine we are testing in this research study is called ChAdOx1 nCoV-19. It has been authorised for emergency use and is currently being used as part of the national vaccination campaign.

ChAdOx1 nCoV-19 is made of two components: the ChAdOx1 virus and an added gene that makes COVID-19 protein.

ChAdOx1 is a weakened version of a common cold virus (adenovirus) that is found in chimpanzees. It has been genetically changed so that it doesn't grow in humans.

To create the vaccine, genes that make Spike protein from the COVID-19 virus (SARS-CoV-2) have been added to ChAdOx1. Vaccination aims to make the body to recognise, and so develop an immune response to, the spike protein.

Trials of ChAdOx1 nCoV-19, given by intramuscular injection, have shown that it is safe and well tolerated, and that it provides protection against COVID-19 infection. It has now been given to millions of people following government roll-out of vaccination.

We aim to test the safety of this vaccine when it is given via the nose (intranasally), rather than as an injection. This has not been studied in humans before. Studies of similar vaccines given intranasally show that they are safe and well tolerated, but can cause side effects, which are discussed in the later section entitled '*Are there any risks from taking part in the trial?'*

In this study, we will investigate three doses of the vaccine:

1. Lower dose of the vaccine
2. The standard dose of the vaccine (equivalent to that given by injection)
3. An intermediate dose (between standard and lower dose)

Although during a pandemic it would be preferable to give a single dose of vaccine, some data suggests that 2 doses of vaccine might stimulate the immune system more than a single dose. However, we don't know how much of an immune response is needed for protection. For this reason, half the participants in the trial will be randomly allocated to receive a second (booster) dose of the vaccine.

Do I have to take part?

No. It is up to you to decide whether or not to take part. Your decision will not result in any penalty, or changes to your standard medical care. If you do decide to take part, you will be given this information sheet to keep (or be sent it electronically) and will be asked to sign a consent form. You are free to withdraw at any time and without giving a reason, but you may be asked to allow an extra visit for a follow up appointment for safety reasons.

Can I take part?

Adults aged 30-40 years can take part in the study.

N.B. Volunteers already enrolled by 8th April 2021, before the age range was changed, may be between 18-40 years old. In line with this change, any of these volunteers who are below the age of 30 will continue to have follow-up visits but will not receive further vaccinations in the trial.

In order to be enrolled in the study you must:

Be willing to allow the investigators to discuss your medical history with your General Practitioner (GP)
Be willing to practice continuous effective contraception during the study and have a negative pregnancy test on the day(s) of screening and vaccination. (females of childbearing potential only)
Agree to refrain from blood donation during the course of the study

You cannot take part in this study if you:

Are taking part in a COVID-19 drug trial
Have any vaccine in the 28 days before or after the study vaccine
Have previously had other similar vaccines that might affect understanding of your results (e.g. adenovirus vectored vaccines or coronavirus vaccines)
Have received an antibody infusion or blood transfusion in the 3 months before having the study vaccine
Have confirmed or suspected problems with your immune system or spleen (including HIV infection), or Have had recurrent, severe infections, or Have used medications that suppress your immune system in the last 6 months.
Have any autoimmune conditions
Have a history of allergic reactions that are likely to be made worse by any component of ChAdOx1 nCoV-19
Have a history of angioedema
Have a history of severe allergic reaction (anaphylaxis)
Have a nose condition that might interfere with, or be worsened by, having the vaccine (including polyps, recurrent nosebleeds and previous surgery on the nose)
Have a history of cancer (Except basal cell carcinoma of the skin and cervical carcinoma in situ)
Have a history of a serious mental health condition likely to affect participation in the study
Have a bleeding disorder
Continuously take anticoagulant (blood thinning) medication (e.g. warfarin, apixaban, rivaroxaban, dabigatran), or Have ever received unfractionated heparin
Have ever had a major blood clot (e.g. deep vein thrombosis ('DVT'), pulmonary embolism ('PE'), or cerebral venous sinus thrombosis), or Have ever been diagnosed as having antiphospholipid antibodies
Have suspected or known current alcohol or drug dependency, or

Suspected or known injecting drug use in the last 5 years
Have a BMI of less than 18 Kg/m^2 or over 40 Kg/m^2
Are pregnant, breast feeding or intend to become pregnant during the study
Have chronic heart, lung (including mild asthma), gastrointestinal, liver, kidney, endocrine or nervous system disease, or Any other serious chronic illness requiring hospital specialist supervision
Are living in the same household as any vulnerable groups at risk of severe COVID-19 disease (as per public health guidance)
Are in a priority group for COVID-19 vaccination (e.g. health and social care workers)

If you are unsure whether you are eligible to be involved in the study, please contact the study team who will be able to advise you.

What will happen if I decide to take part?

If you are interested in taking part in the trial, we will ask you to compete a short online questionnaire to check that you meet the criteria for the trial. If you are eligible, you will be invited to a screening visit.

Screening Visit (approximately *1.5 hours)*

Below is an outline of what to expect from your screening visit. Your ID will be checked at this visit.

Video presentation

- We will ask you to watch a video presentation with information about the study to ensure you understand what to expect by taking part, the risks involved and what side-effects you might expect to experience.
- You will be able to ask any questions you have to a member of the research team

Consent

- If, following this, you decide to take part, you will be asked to sign the consent form.
- You may also be asked to complete other paperwork
- You will also be asked to agree to allow the research team to contact your own Doctor (GP) to make sure there are no medical reasons why you should not participate.

Medical history and examinaion

- You will be asked questions about your current health and any past medical problems
- A doctor will perform a physical examination. This may involve listening to your heart and lungs with a stethoscope, examining your abdomen and feeling for lymph nodes around your neck.
- Your height, weight, temperature, blood pressure and pulse will be recorded.

Blood and urine tests

- Blood samples will be taken to check your general health and immune responses.
- We will also ask you for a sample of urine. This will be tested for protein, blood and sugar. It will also be used to do a pregnancy test for females of childbearing potential.

Abnormal test results

Blood tests will include tests to check for anaemia, for normal kidney and liver function and for exposure to the viruses HIV (the virus that leads to AIDS), Hepatitis B or Hepatitis C (viruses which affect the liver).

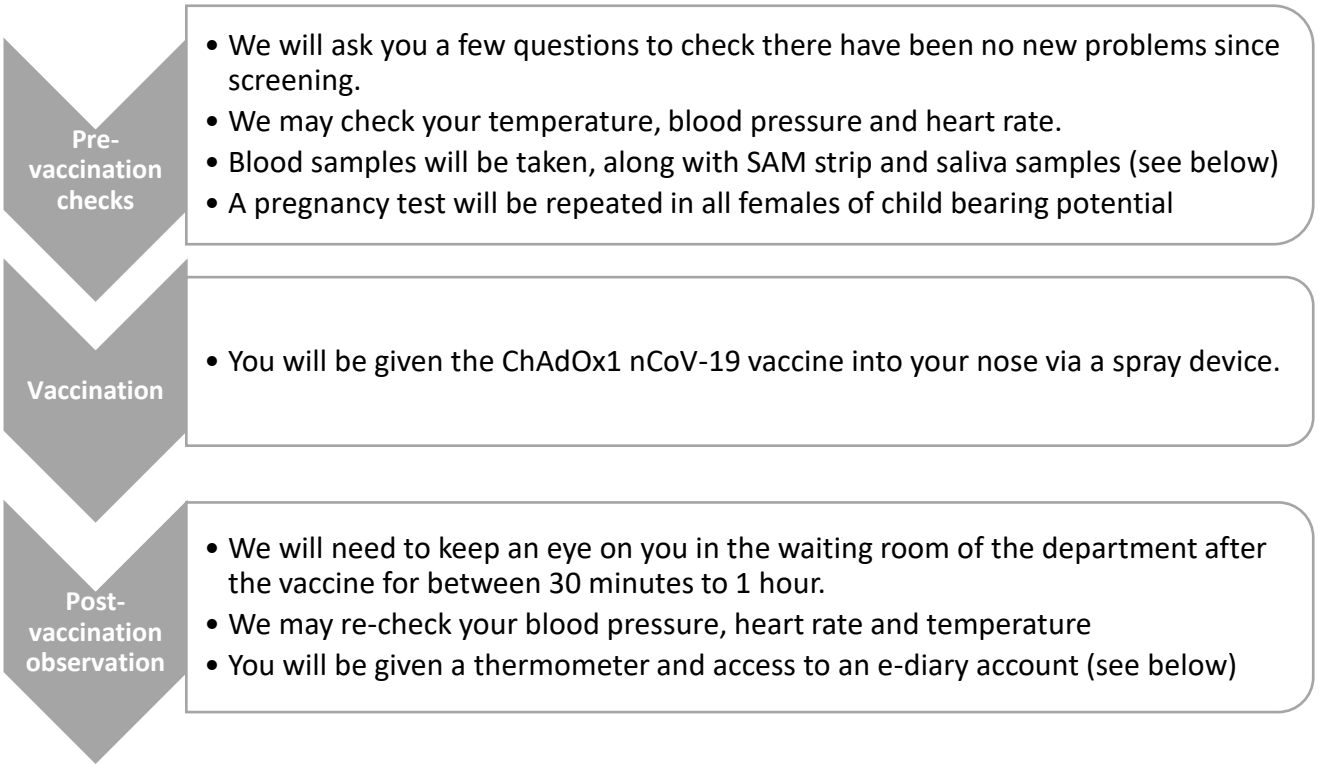
If you have a positive test for one of these viruses, we will inform you of the result. With your permission we will offer referral for medical review, confirmation of the result, and treatment if necessary.

Sometimes minor abnormalities can be found with the blood tests. In this situation you may be asked to return for a repeat blood test so that it can be checked again.

If test results are abnormal you may not be able to participate in the study. We will ask your permission to contact your GP or a specialist doctor, whichever is the most appropriate, to ensure the abnormality is followed up.

Once all your test results have been checked, if no problems have been highlighted, you will be contacted to arrange a date to start the trial. If you qualify to be in the trial, we will invite you to a vaccination visit (Day 0).

Vaccination Visit (Day 0) (approximately 2 *hours)*



Half of participants will be randomly allocated to receive a second vaccine on day 28. This visit will be the same as the first. Allocation will take place at the first vaccination appointment.

Electronic Symptom Diary "e-diary"

We will give you a thermometer and an E-diary account to record all your symptoms and your temperature every day for 7 days after vaccination. You have the option to continue to record symptoms for up to 28 days following vaccination.

You will also be asked to record in the diary any serious medical illnesses or hospital visits you may have over the course of the study. This may include information about any COVID-19 symptoms or test results that you may have.

SAM strips & nasopharyngeal samples.

Nasosorption is a method used to sample fluid from inside the nose, allowing us to study immune responses. A SAM strip is similar to a nasal swab. It is inserted into a nostril and kept there for 60 seconds before being removed.

We will also ask some volunteers to provide nasal swab samples, similar to COVID swabs, or samples collected by gently brushing the lining of the nose.

Saliva samples

Saliva will be collected by asking you to gargle water, which is then collected in a container.

Follow-up visits *(up to 30 minutes)*

Following vaccination, we will ask you to attend a series of short follow-up visits.

During these visits, we will check everything is fine and discuss any symptoms. We may also ask you about any COVID-19 tests or symptoms that you may have. You may have blood, SAM strip, nasopharyngeal and/or saliva samples taken.

Some of these appointments will be at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM), at the Churchill Hospital. Other appointments may be conducted by phone or video call to reduce the number of times you need to attend the building.

We may ask you to take SAM strips and saliva samples at home. You will be provided with appropriate training and guidance if this is the case. We may ask to guide and monitor you taking these samples at home by video call.

The full schedule of visits can be seen below.

Schedule of visits:

Participants will be divided into 3 groups:

Group 1 (1a/1b)	• **Low** dose ChAdOx1 nCoV-19. • 6 volunteers (1a: 1 volunteer, 1b: 5 volunteers)
Group 2 (2a/2b)	• **Standard** dose ChAdOx1 nCoV-19 (equivalent to dose given by injection) • 24 volunteers (2a: 3 volunteers, 2b: 21 volunteers)
Group 3	• **Intermediate** dose ChAdOx1 nCoV-19 (between standard and low dose) • 24 volunteers

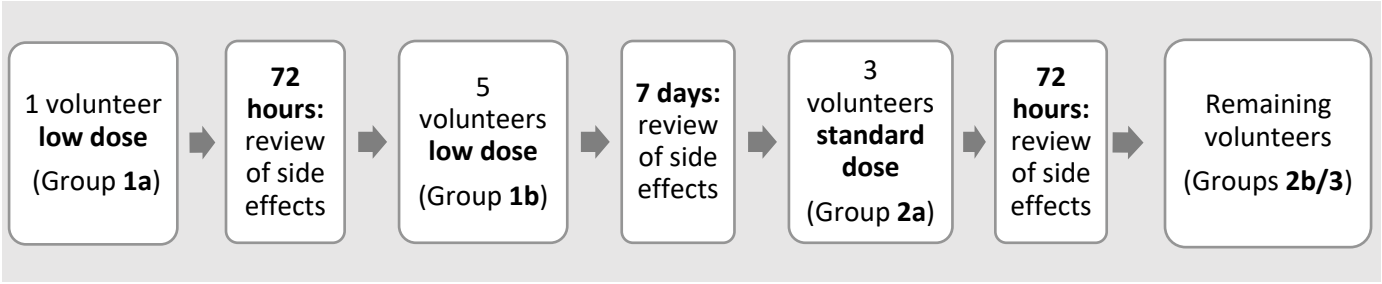
Groups will be vaccinated in the following order:

Subgroup 1a will have a single participant. This participant will receive the low dose of vaccine and be reviewed within 72 hours by a study doctor for any effects. Following satisfactory review, the participants in group 1b will be vaccinated.

Following review of all participants in group 1, Subgroup 2a will be vaccinated. Subgroup 2a will consist of 3 participants who will receive the standard dose of vaccine. These participants will also be reviewed by a study doctor for any side effects within 72 hours.

Following satisfactory review, the remaining participants (groups 2b and 3) will be vaccinated.

This process is summarised in the diagram below:



Following the process described above, visits will proceed as previously outlined. Half the participants in each group will be randomly allocated to receive a second (booster) vaccine.

The schedule and total number of study visits for each group can be seen below:

Visit Number	**1**	**2**	**3**		**4**	**5**	**6**	**7**	**8**	**9**	**10**	**Total visits**
Timeline (days)	Screening	0	1*	3**	7	14	28	35	42	56	112	
Single nasal vaccine		**N**										7-8
Two nasal vaccines		**N**					**N**					9-10

*Key: shaded boxes: appointments, N: intranasal vaccination; * selected participants in groups 2b/3 only, ** 1a and 2a only*

Day 1 visit: Selected participants in groups 2b and 3 only may be asked to provide nasopharyngeal or brush samples the day following vaccination

Day 3 visit: Participants in groups 1a and 2a only will be reviewed within 72 hours of vaccination as previously described

Additional visits may be organised up to twice a week if new information indicates it would maximise participant safety.

Considerations before taking part in this study

Blood Donation: Under current UK regulations, participants will not be able to donate blood during the course of the study.

Private Insurance: If you have private medical or travel insurance you are advised to contact your insurance company before participating in this trial, as involvement may affect the cover provided.

What should I avoid during the trial?

You should not donate blood during the trial or take part in other studies that involve blood sampling or the administration of drugs or vaccines, including trials testing other interventions for COVID-19.

If during the trial you require any vaccinations for health, travel, or occupational reasons, you should inform the Investigators beforehand. We will discuss with you the most appropriate time to receive them.

Approved COVID-19 Vaccinations

We are aware that participants in the trial may become eligible for approved COVID-19 vaccinations through the NHS. If you are offered an approved COVID-19 vaccine whilst you are participating in the trial we will ask that you:

- Do not have other COVID-19 vaccines within 28 days of receiving a dose of the study vaccine,
- Notify the study team

Participation in the trial should not interfere with you having an approved vaccination outside the period stated. If you are offered a vaccine whilst in the trial, please contact the study team to discuss it.

Please note that intranasal vaccination in this trial is not considered an approved vaccine.

Are there any risks from taking part in the trial?

The risks and side effects of the proposed vaccinations and trial procedures are detailed here:

Blood samples

Drawing blood may cause slight pain or bruising at the site where the needle enters. Rarely, people feel light-headed or faint. During the trial, we will take between 5ml (approximately 1 teaspoon) and 60ml of blood (approximately 4 tablespoons) at a single visit. The total amount taken over the period of the trial may be around 399ml. This will depend on which group you are in and whether you have a booster vaccination.

We will discuss any abnormal test results or new diagnoses that occur during the trial with you. If you agree, we will inform your GP (or a hospital specialist, if more appropriate). Any newly diagnosed conditions will be looked after within the NHS.

Participants will not be informed of the results of their levels of immunity against the COVID-19 virus.

Vaccination Side Effects

It is likely that you will experience some symptoms at the vaccination site as well as general symptoms due to vaccination.

We expect that symptoms will be mild most of the time, although some may be moderate or severe. There is a chance you could experience a side effect that is more severe than those described below, or that has not been seen before. All symptoms should resolve completely within a few days.

The chimpanzee adenovirus has been weakened so that it cannot grow in human cells. The SARS-CoV-2 protein it carries cannot cause COVID-19 disease.

Local Reactions at vaccination site

It is important to remember ChAdOx1 nCoV-19 has not previously been given via the nose and therefore the amount of safety data available are limited. From similar trials, the symptoms you may experience are: sneezing, sore throat, nasal discharge, irritation, tenderness or pain.

General reactions

During the first 24-48 hours after vaccination you may experience flu-like symptoms such as muscle aches, joint aches, feverishness, chills, headache, nausea, tiredness and/or feeling generally unwell. These symptoms should usually resolve within a few days and can be experienced whichever vaccine you are given.

Fever is a common side effect of vaccination. If you develop fever in the first 24-48 hours post-vaccination, you should enter this information into the ediary. You and your household members should immediately self-isolate. If the fever does not continue, it is likely to be a vaccine effect and you

can carry on as normal once you have been without a temperature for 24 hours. If the fever continues, you should continue to self-isolate and arrange COVID-19 testing as per government guidance. If you are unsure about this, you can contact the study team.

Serious Reactions

With any vaccination there is a risk of rare serious adverse events, such as an allergic reaction. These may be related to the immune system or to the nervous system. Severe allergic reactions to vaccines (anaphylaxis) are rare, but can be fatal. In case of this unlikely event, medication for treating allergic reactions is available and the investigators are appropriately trained in the management of anaphylaxis.

Reactions in the nervous system are also extremely rare, but can include an illness called Guillain-Barré syndrome, a condition in which people can develop severe weakness and can be fatal. These adverse events have not previously been seen following administration of similar vaccines using ChAdOx1 as a viral vector.

In the studies using ChAdOx1 nCoV-19 as an intramuscular injection, safety reviews were undertaken when volunteers developed unexplained neurological symptoms, including changed sensation or limb weakness. These studies were paused while a safety review took place. Independent review concluded that these illnesses were either unlikely to be associated with the vaccine, or that there was not enough evidence to say if they were or were not related to the vaccine. In each of these cases, after considering the information, the independent reviewers recommended that vaccinations should continue.

With any new medicine or vaccine there is always a possibility of an unexpected side effect.

You will be provided with a 24h study mobile number. If you experience unexpected events or are concerned you can use this to contact one of the study doctors at any time. We will ask you to record these symptoms in the E-Diary too.

Frequently asked questions

Could this vaccine increase my risk of developing blood clots?

Problems with blood clotting have been seen in some people who have received this vaccine by injection. It is possible that this may be a very rare side effect of this vaccine. These problems can be serious or fatal.

The best estimate that we can currently make is that, within the age group eligible for this study, serious problems may occur in around 1 in every 100,000 recipients of the vaccine. We do not know whether these clots will be more or less common after intranasal administration of the vaccine.

Though it is unlikely that anybody in this small clinical trial would suffer such side effects, we will monitor participants closely and urgently assess anyone with symptoms, to diagnose any problems earlier than might happen outside a trial.

You must contact the study team immediately if you develop any of the following symptoms in the 28 days following vaccination:

- Severe or persistent headache that does not respond to simple painkillers
- Shortness of breath, chest pain or persistent abdominal pain, leg swelling
- Blurred vision, confusion or seizures
- Unexplained pin-prick rash or bruising

Could immunisation with ChAdOx1 nCoV-19 make COVID-19 disease worse?

In the past, experimental vaccines were developed by different research groups against the SARS virus, which is in the same family as the COVID-19 virus and also infects the lungs. In some cases, animals that received certain types of experimental SARS vaccines appeared to develop *more severe* lung inflammation when they were later infected with SARS compared with unvaccinated animals. These problems have not been seen in clinical trials, routine use, or animal studies of ChAdOx1 nCoV-19 vaccine. We therefore think this is not a significant risk but will continue to monitor for any signs.

Could immunisation cause me to develop antibodies to the vaccine virus?

Vaccination with a viral vector can cause you to develop antibodies to the vector virus (in this case, ChAdOx1) as well as the intended target of the vaccine (SARS-CoV-2 Spike protein). There is some concern that these antibodies may then make subsequent doses of the same vaccine less effective. In a trial of a similar vaccine, intranasal vaccination did generate antibodies to the vaccine virus. These, however, did not reduce the immune responses in these participants when they were given a second dose of the vaccine as an injection. We hope that this will be the same for the ChAdOx1 nCoV-19 vaccine.

What are the advantages of taking part?

You will not necessarily gain any direct benefit from the trial, but the information gained from the study might help to develop an effective vaccine against COVID-19.

If, in the future, you become exposed to COVID-19, you should not assume that the vaccine you received in this study will give you any protection against COVID-19.

What should you do if you believe you may have developed COVID-19 during the study?

If you believe that you may have COVID-19 while enrolled in the study then you must immediately inform the study team on 01865 617799.

Do not attend the clinical trial site unless you have been informed to by the study team.

If you are at all unsure please contact the study team.

We will ask you to provide information about any COVID-19 tests you have, along with symptoms.

It is important that you understand that if you do become seriously unwell and need to be admitted to hospital, the standard referral routes within the NHS will be used. Participants will be treated the same way as the general population in this context of the COVID-19 pandemic. We are unable to offer extra medical support outside what is available within the NHS for the general public.

Will I be paid for taking part in this trial?

You will be compensated for your time, the inconvenience of having blood tests and procedures, and your travel expenses. The total amount compensated will be up to £535, depending on the number of visits you are asked to attend.

Trial reimbursement will be made by bank transfer within six weeks of your completion of the trial, so please bring your bank details with you to your screening visit (no cash payments can be made). Should you decide to withdraw from the trial before it is completed, payment will be *pro rata* (you will receive a proportion of the total amount).

What if new information becomes available?

Sometimes during the course of a trial, new information relevant to the trial becomes available. If this happens, we will tell you about it and discuss whether you want to, or should, continue in the study. If you decide to continue to take part, you will be asked to sign an updated consent form. On receiving new information, we may consider it to be in your best interests to withdraw you from the study. Your participation in this study may also be stopped at any time by the study doctor or the Sponsor for other reasons.

What will happen if I don't want to carry on with the trial?

If, at any time after agreeing to participate, you change your mind about being involved with this study you are free to withdraw without giving a reason. If you withdraw we would not usually perform any more research procedures, although occasionally we might need to offer you a follow up visit for safety purposes, for example to check a blood result. Your decision will not result in any penalty. Unless you state otherwise, any blood taken whilst you have been in the study will continue to be stored and used for research as detailed above. You are free to request that your blood samples are destroyed at any time during or after the study. If you choose to withdraw from the trial, your standard medical care will not be affected.

What if something goes wrong?

The investigators recognise the important contribution that volunteers make to medical research, and make every effort to ensure your safety and well-being. The University of Oxford, as the research Sponsor, has arrangements in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial.

In the event of harm being suffered, while the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment which may be provided if you needed to be admitted to hospital.

Complaints statement

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the research investigators who will do their best to address your concerns by sending us an email to vaccinetrials@ndm.ox.ac.uk. Alternatively you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or the head of CTRG, email ctrg@admin.ox.ac.uk

Will my participation in this trial be kept confidential?

All information that is collected about you during the course of the research will be coded with a study number and kept confidential. The information is available to the trial team, authorised collaborators, ethical review committees, Oxford University Hospitals NHS Foundation Trust, government regulatory agencies and the Sponsor (University of Oxford), who can ask to access the trial data. Responsible independent monitors may be given access to data for monitoring and/or audit of the trial to ensure we are complying with regulations. They are bound by the same confidentiality rules. The electronic diary is sent to you by email to complete online. Your email address will be stored on a secure University of Oxford server, access to the diary system is password controlled and only study site staff and sponsor IT management can view the email address.

Every effort will be taken to maintain confidentiality. Information about you may be stored electronically on a secure server, and paper notes will be kept in a key-locked filing cabinet or restricted access office

at the Oxford Vaccine Centre or at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM), University of Oxford. Trial results will be published in a scientific journal but nothing that could identify you will be included in any report or publication.

What will happen to my data?

This study complies with the UK General Data Protection Regulation (UK GDPR) and Data Protection Act 2018. Use of your personal information will be minimised by using participant study numbers on most documents. UK Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.'

The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you such as contact details for a minimum of 5 years after the study has finished. The need to store this information for longer in relation to licensing of the vaccine will be subject to ongoing review. De-identified research data will be stored indefinitely. If you have agreed that samples can be retained for future research then your personally identifiable information will be kept with restricted access solely for the purposes of sample management for a minimum of five years after the last sample has been either used or disposed of in order to meet regulatory requirements. Samples will be provided for future research only in a form that does not identify you.

We store research data securely at the University of Oxford indefinitely following removal of identifiable information. If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.

The study team will use your name and contact details, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, in relation to your health during the study and to oversee the quality of the study.

At the completion of the study, unless you consent otherwise (e.g. if you request to be informed of other trials), your personal details will not be used to contact you other than exceptional circumstances concerning your safety. If you consent to take part in another study carried out by the Oxford Vaccine Centre, personal information and medical information including blood test results may be accessed to avoid unnecessary repetition.

Your bank details will be stored for 7 years in line with university financial policy.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: https://compliance.web.ox.ac.uk/individual-rights

Involvement of the General Practitioner (GP)/Family doctor (GP)

In order to enrol into this study, you will be required to sign a form documenting that you consent for us to contact your GP and to access an electronic summary of your medical history ('NHS Summary Care Record'). This is to inform them that you are interested in being involved in the study, and to check there are no medical reasons that they are aware of that would make your participation inadvisable. Your GP may be asked to share information about your medical history and give access to any other medical records as required. The researchers will not enrol you in the trial if your GP has relevant concerns about

your eligibility or safety. We will write to your GP to let them know about your enrolment and study completion status, so they can update your medical records accordingly.

If you have up to date copies of your medical records or GP summary records please bring these to your screening visit.

What will happen to any samples I give?

If you consent, some of your leftover samples can be stored and used for future infectious disease or vaccine-related research. This is optional; your participation in this study will not be affected by your decision whether to allow storage and future use of your leftover samples. Upon your request at any time, your remaining samples will be destroyed.

To avoid repeat testing, if you are not enrolled into this study and you apply to enter another study conducted by the Oxford Vaccine Centre based at the Centre for Clinical Vaccinology and Tropical Medicine (CCVTM), the results from your screening visit blood tests may be used to determine whether you are eligible for the trial you applied for.

Your study samples will be analysed in the site Oxford University Hospitals NHS Foundation Trust laboratories, Oxford University research laboratories or other specialist laboratories. Other tests to look at the response of your body to the vaccine or to COVID-19 will be done with collaborating laboratories in the UK and in other countries, including the United States. Any samples or data sent to them would not include information that identifies you.

Will any genetic tests be done?

We may do genetic tests on your blood samples to look at the patterns of genes that regulate your individual immune response (these are called Human Leukocyte Antigen genes). Doing this helps us to work out which aspects of the immune response to vaccines are due to genetic differences between individuals. We may also look at the expression of certain genes which relate specifically to the immune response to COVID-19, but no genetic tests concerning diseases or conditions other than COVID-19 and other vaccine related responses.

What will happen to the results of the research study?

The results of this research study may be presented at scientific meetings or conferences and published in a scientific medical journal. This may not happen until 1 or 2 years after the study is completed. If you contact the researchers in the future, you can obtain a copy of the results. You will not be identified in any report or publication.

The de-identified data from this study will be shared with the collaborating partners who are organising and funding this research work. Data from this study may be used to file patents, licence vaccines in the future or make profits in other ways. You will not be paid for any part of this. Data from this study may be used as part of a student post-graduate degree, for example a MD or PhD.

Taking part in future vaccine-related research

With your consent, we would like to keep your contact details after your participation in this study is complete, so we may inform you of opportunities to participate in future vaccine-related research. This is entirely optional and your participation in this study will not be affected by your decision to allow or not allow storage of your contact details beyond your participation in this trial.

Your details will be stored electronically on a secure server and only authorised individuals at the Oxford Vaccine Centre will have access to it. We will not, under any circumstances, share your contact details with any third party institutions without your permission. Being contacted does not oblige you to agree

to take part in future research and you can ask us to have your contact details removed from our database at any time.

Who is sponsoring, organising and funding the research?

The study is organised and sponsored by the University of Oxford. The study is funded by AstraZeneca and the University of Oxford. Neither your GP nor the researchers are paid for recruiting you into this study.

Who has reviewed the study?

This study has been reviewed by the NHS Research Ethics Service (RES) (REC reference 21/HRA/0699). The Medicines and Healthcare products Regulatory Agency (MHRA), which regulates the use of all medicines in the UK, has reviewed the study design and has granted permission to use this vaccine in this clinical study.

Further information and contact details

We hope this information sheet has answered all of your questions. If you would like further information about participating in research please visit the following website: http://www.nhs.uk/conditions/Clinical-trials/Pages/Introduction.aspx. For independent advice about participating in this trial you may wish to contact your GP.

If you would like to speak to one of our team members to discuss any aspect of this trial or **if you are interested in taking part in the study, please contact us**:

Phone number: 01865 617799

Email address: vaccinetrials@ndm.ox.ac.uk

Website:
www.jenner.ac.uk/volunteer/recruiting-trials/covid-19-vaccine-intranasal-study-cov008