Please print on local hospital headed paper

Rapid Protection

RAPID-PROTECTION: an adaptive clinical trial of Evusheld and COVID-19 vaccination in immunosuppressed patients highly vulnerable to infection with COVID-19

Patient Information Sheet V4.0 13/01/2023

Trial Summary

- The RAPID-PROTECTION study is trying to find a new way to protect patients who may be more vulnerable to developing severe COVID-19.
- This study is testing a monoclonal antibody called Evusheld (also known as AZD7442). This is a laboratory-made protein that mimics the immune system's ability to fight off harmful pathogens such as viruses
- Evusheld has been shown in clinical trials conducted whilst earlier COVID-19 variants were in circulation, to prevent COVID-19 infection for up to 6 months after a single dose in healthy volunteers.
- We want to find out if Evusheld in combination with a COVID-19 vaccine improves immune protection against the current COVID-19 variants in immunocompromised patients.
- The study will determine the levels of immune protection that Evusheld offers patients at risk of COVID-19 infection using laboratory based tests.
- In the study, all patients will receive the antibody Evusheld via intramuscular injections. You will be asked to stay in the hospital for 15 minutes after the injections.
- Participants will be randomly allocated to one of two COVID-19 booster vaccinations which will be given 28 days after the Evusheld injections.
- You will be asked to attend the clinic to provide blood samples 7 times over the space of one year to check the levels of Evusheld and to examine your immune responses against COVID-19. You will be compensated for your time.
- You will be asked to complete questionnaires at four timepoints throughout the study
- Your study doctor will monitor your safety and well-being throughout the study.

Invitation to participate

We would like to invite you to take part in this research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take the time to read this information sheet carefully. You can also discuss this study with other people such as your family or friends if you wish. One of the doctors or nurses will go through the information sheet with you and answer any questions that you have. If you decide to participate in this study, you will be asked to complete a consent form. Thank you for taking the time to read this information sheet.

Background to Evusheld

The RAPID-PROTECTION study is trying to find a new way to protect patients who may be more vulnerable to developing severe COVID-19 due to current health conditions. Despite repeated vaccinations against COVID-19, some people with impaired immune systems caused by conditions such as cancer, inflammatory conditions, and those with organ transplants and other serious health conditions, remain at high risk of catching COVID-19 and becoming unwell.

Evusheld is a long-acting antibody treatment which prevents COVID-19 infection. It reaches effective levels in the body within a few hours after the injection, giving protection almost immediately. Evusheld has already been approved for use in the United States and the UK for the prevention of COVID-19 in immunocompromised people.

Several of the studies looking at Evusheld protection were conducted whilst earlier COVID-19 variants were in circulation, for example in the phase III PROVENT trial. In this trial, a single dose of 300mg of Evusheld reduced the risk of developing symptomatic COVID-19 by 77% when compared to a placebo, with protection lasting for at least 6 months. There were no cases of severe COVID-19 in those treated with Evusheld and the results show the side effects experienced were similar between the placebo and Evusheld groups.

The virus has since continued to evolve with a number of different variants in circulation including Omicron. Although we do know that Evusheld is effective against the current Omicron COVID-19 variants BA.4, BA.5, BA.1 and BA.1.1, the sensitivity of Evusheld against these variants is reduced. We also do not know how long the protection will last in immunocompromised people.

Emerging real world data, data from ongoing studies such as PROVENT and TACKLE, and scientific modelling suggests that increasing the dose of Evusheld from 300mg to 600mg should give 6 months of protection against COVID-19 as it continues to evolve. The higher dose of Evusheld (600mg) was found to be well tolerated and comparable to the lower dose of Evusheld (300mg).

This study will help improve our understanding of Evusheld and how well it works against emerging COVID-19 variants in immunocompromised people.

About the research

What is the purpose of the research?

Although we know that Evusheld does provide protection, we do not know how long for in people who are immunocompromised. This study will look at the levels of Evusheld over time in immunocompromised participants using blood tests. It will also test whether this protection can be further enhanced by giving a COVID-19 vaccine booster.

You have been asked to take part in this clinical research study because you have been identified as vulnerable to COVID-19 due to your current health conditions.

What would my involvement be?

What would I be asked to do if I took part?

If you are eligible for the study, you will be asked to attend clinic to receive Evusheld. During this visit, your treating team will explain what to expect in the study, the risks involved and what side affects you might experience. You will also have the opportunity to ask any questions you may have.

To take part in the study, you will need to:

1. Provide written informed consent by signing the end of this document.
2. Be able and willing (in the Investigator's opinion) to comply with all trial requirements.
4. Be able and willing to practice continuous effective contraception during the first 3 months of the trial and, if appropriate, a negative pregnancy test on the day of screening. There is more information on this on page 10 of this participant information sheet.
5. Provide access to all medical records with respect to current and past medical treatments.
6. Have one or more of the following eligible conditions: haematological malignancy, solid tumour, renal disorder, hepatic disorder and/or inflammatory disorder.
7. Be over 18 years old.

If you decide to take part in the study, you will be asked to sign the consent form and your General Practitioner will be notified of your participation. The treatment you are receiving for your current health condition will not be affected by your participation in the study.

Treatment will continue as intended by your treating doctor. If you sign the consent form a member of the medical team would check details of your medical history, and may perform a physical examination; which could involve listening to your heart and lungs with a stethoscope, examining your abdomen as well as feeling for lymph nodes around your neck and in your armpits. We will measure and record your;

· Height
· Weight
· Temperature
· Blood pressure
· Pulse rate
· Respiratory rate
· Non-invasive blood oxygen level (saturations)

You may then be asked to take a pregnancy test (where applicable) to make sure you are not pregnant. Blood samples will be taken just before you receive Evusheld to check whether you have previously been infected with the COVID-19 virus (antibody test) and to check on your blood, liver and kidney function. You may also be given a lateral flow test for COVID-19 to see if you have a current infection. If the lateral flow test is positive for COVID-19 infection, you will also be asked to provide a PCR swab.

You will then receive Evusheld (600MG) by intramuscular injections. You can choose whether you wish to receive the injection as four injections into your arms (two in each arm), or as two injections into your gluteal muscle (buttocks). The person administering the Evusheld will discuss this with you before you have the injections. We will ask you to stay at the clinic for 15 minutes so that we can check on how you are. During this time, we will ask you to complete three questionnaires.

14 days later, you will be contacted by your treating team who will ask you about how you are feeling and if you have had any side effects.

28 days after the Evusheld injection you will be asked to attend clinic to provide a blood sample and to receive your COVID-19 booster vaccine (Moderna bivalent Original/Omicron vaccine or Pfizer/BioNTech bivalent Original/Omicron BA.1 vaccine). The type of vaccine booster you will receive will be randomly selected by a computer. The vaccine will be administered as directed, by your study doctor through an injection in your arm. Your doctor will inform you which vaccine you have been allocated to as part of the study.

You will be asked to attend the clinic for follow up visits so that we can check how you are, to check on your symptoms and to provide further blood samples. These will be scheduled at 56, 112, 180, 273 and 364 days post injection to check the levels of Evusheld and to examine

your immune responses against COVID-19. At these visits, you may be asked to complete a questionnaire and given a lateral flow test for COVID-19 infection. If the lateral flow test is positive for COVID-19 infection, you will also be asked to provide a PCR swab.

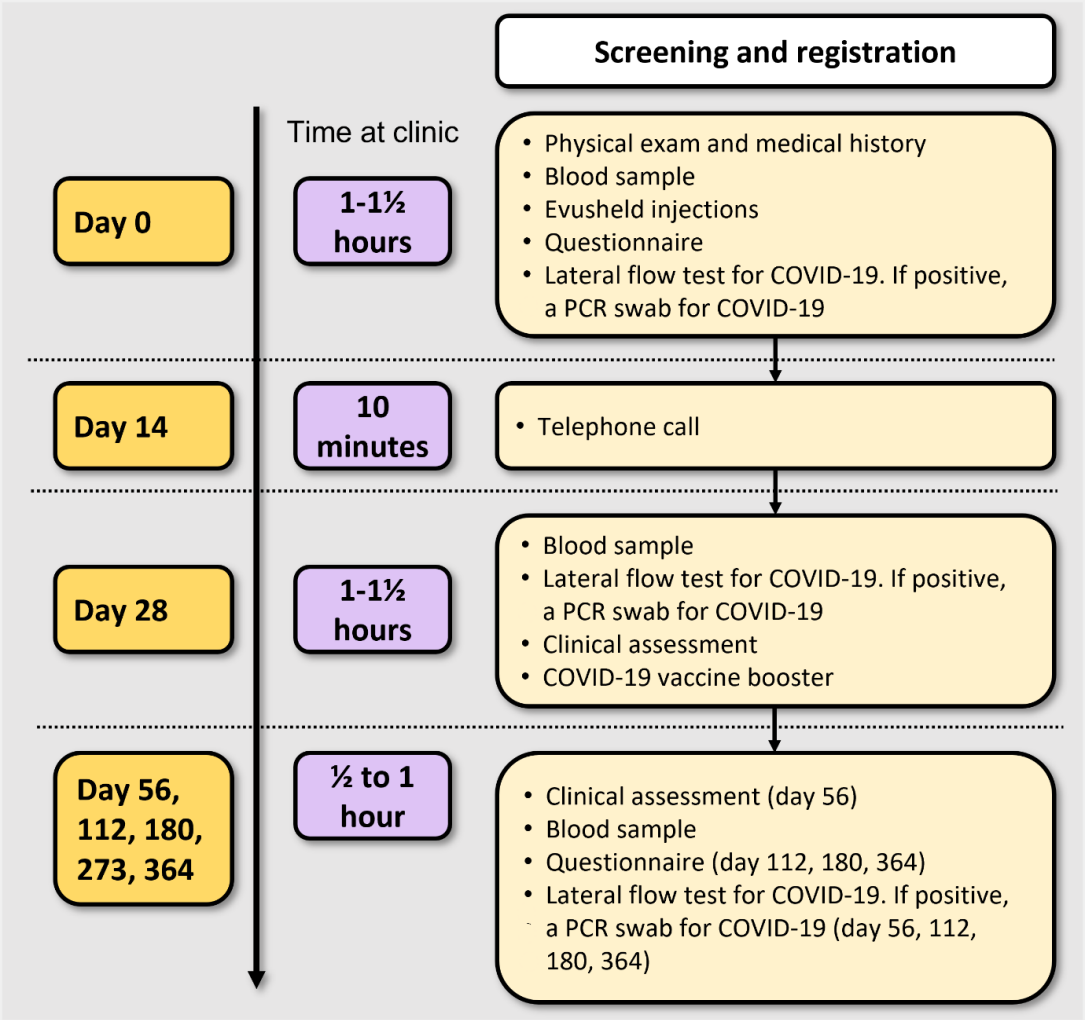
If you become symptomatic for COVID-19 during the study you must take a lateral flow test and self-report the result to the study team. In this eventuality, you will be asked questions about the severity of your symptoms and will be required to take a nasal swab at home, and return this in the freepost packaging to the laboratory for PCR testing. The materials and instructions for collecting, packaging and posting swabs will be provided to you as part of the study.

You are encouraged to keep a supply of lateral flow tests at home whilst you are on the study. We advise you to regularly order via the NHS website: www.gov.uk/order-coronavirus-rapid-lateral-flow-tests.

If you agree to take part in this study, you must come to the hospital at the times agreed with your study doctor as the information we will collect at these appointments are critical for answering the question of the study. It is important that you follow the instructions from your study doctor. It is also important that you tell the study staff about your health, any new side effects, injury, or symptoms that you have as well as any medicines, vitamins, or herbal supplements that you are taking before and during the study. There are some medicines that should not be taken during the study, and for up to three months after the last dose of study medication (e.g. certain vaccinations). You should discuss any new medicines with your study doctor. You can speak with your study doctor by using the contact numbers at the end of this information sheet.

The diagram below provides an overview of the hospital visits you will be expected to attend if you decide to take part in the study:

Varley M, *et al. BMJ Open* 2025; 15:e084345. doi: 10.1136/bmjopen-2024-084345



What will the questionnaires involve?

The questionnaires will be given to you in clinic at your treatment visit, and at 112, 180, 364 days after the Evusheld injection. The questionnaire should take about 10-15 minutes to complete.

The questionnaires ask about your household, behaviour changes due to the COVID-19 pandemic and your general health and wellbeing. Your unique trial number will be collected, in addition to your partial date of birth (mm/yyyy), when completing the questionnaires to link your trial data. The collection of partial date of birth on these questionnaires is as an extra cross check to ensure that the correct data is being collected for the correct participant and will not be used for any other reason.

What if I become eligible for routine immunisation against COVID-19 whilst enrolled in the study?

Participation in this study means that, unless the study team specifically advise otherwise, you **will not** be able to receive any of the approved NHS COVID-19 vaccines for three months after receiving your booster vaccine on this study. Additional vaccines may affect the results of the study and not give an accurate picture of the protection provided by Evusheld.

What are the possible benefits of taking part?

We know from other studies that Evusheld protects people from getting severe COVID-19 infections for 6 months to 12 months. However, we do not know how long this protection lasts in people who are immunocompromised and how well it works against emerging COVID-19 variants. This is one of the questions we aim to answer as part of this study. Because we cannot guarantee how long you will be protected for, you should continue to follow the COVID-19 government guidelines for immunocompromised patients, for example, on isolation and shielding.

You may benefit from having an additional COVID-19 vaccine booster although the effect of the vaccine following Evusheld is unknown.

Taking part in this study will mean that you are contributing to research that may benefit many people who are immunocompromised during the COVID-19 pandemic. We may also find out more about how mono-clonal antibodies and the immune system works which may improve research in the future.

What are the possible side effects, disadvantages, and risks of taking part?

The disadvantage in taking part in this study may be the risk of having the side-effects from Evusheld and/or the COVID-19 booster vaccine.

Potential risks from Evusheld (Frequency unknown)

Evusheld has been given to 10,000 participants, a number of which had compromised immune systems, as part of other studies and is considered to be safe. Similar to other monoclonal antibodies and to other medications, there is a risk that the drug may have side effects. These may be mild or severe and may occur within hours or days after the injection. Symptoms may include joint pain and swelling, fainting, dizziness, hives or rash. It may also cause redness, itching, tenderness, or a rash where the injection is given.

As with all the COVID-19 vaccines, there is a there is a small risk of rare serious side effects, such as an allergic reaction. These may be related to the immune system or to the nervous system. Severe allergic reactions to vaccines and mono-clonal antibodies are rare (approximately 1 per million vaccine doses, unknown in Evusheld).

Varley M, *et al. BMJ Open* 2025; 15:e084345. doi: 10.1136/bmjopen-2024-084345

Serious allergic reactions may include anaphylaxis. Anaphylaxis is a life-threatening allergic reaction, which would be diagnosed by a doctor. The initial symptoms may include difficulty in breathing, swelling of the lips, a drop in blood pressure and a rash. After receiving the study drug you will be monitored for any immediate signs or symptoms of an allergic reaction. Without immediate medical treatment this condition can be fatal. In case of this unlikely event, medication for treating allergic reactions is available and the researchers are appropriately trained in the management of anaphylaxis.

If any serious allergic reaction occurs after receiving the first injection, the next injection will not be given to you and the study doctor will monitor you for safety.

For possible delayed allergic reactions (not detected during your visit), please inform your doctor immediately if you think you may be having a reaction.

Serious cardiac adverse events have happened, but were not common, in people who received Evusheld and also in people who did not receive Evusheld in the clinical trial studying pre-exposure prophylaxis for prevention of COVID-19. In people with risk factors for cardiac events (including a history of heart attack), more people who received Evusheld experienced serious cardiac events than people who did not receive Evusheld. It is not known if these events are related to Evusheld or underlying medical conditions. Contact your healthcare provider or get medical help right away if you get any symptoms of cardiac events, including pain, pressure, or discomfort in the chest, arms, neck, back, stomach or jaw, as well as shortness of breath, feeling tired or weak (fatigue), feeling sick (nausea), or swelling in your ankles or lower legs.

You may also experience low platelets (cells that help the blood to clot) which can lead to bleeding in the mouth, gums, bruising, nose bleeds, and pinpoint red spots on the skin. Patients that develop these types of reactions during the course of the study are advised to seek immediate medical help in managing their medical condition.

These are not all the possible side effects of Evusheld. Not a lot of people have been given Evusheld. Evusheld is still being studied so it is possible that all of the risks are not known at this time.

Vaccination Side Effects (Pfizer BioNTech bivalent Original/Omicron vaccine, Moderna bivalent Original/Omicron vaccine)

Very Common side effects (may affect more than 1 in 10 people)

Some people can develop these symptoms after vaccination. They usually last for less than a week after you are vaccinated (more commonly 24-48 hours afterwards). The majority of these symptoms can be reduced by use of paracetamol around the time of immunisation and over the next 24 hours.

Varley M, *et al. BMJ Open* 2025; 15:e084345. doi: 10.1136/bmjopen-2024-084345

- People very often have tenderness, pain, warmth, redness, itching, swelling, or bruising or less commonly have a small lump in their arm where they have been vaccinated.
- Fatigue
- Headaches
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough, and chills
- Muscle aches, Joint aches, and stiffness
- Feeling unwell (malaise)
- Feeling sick or nauseated or vomiting
- Diarrhoea

Uncommon side effects(may affect up to 1 in 100 people)

- Sleepiness, feeling dizzy, or deep unresponsiveness and inactivity
- Decreased appetite
- Abdominal pain (*Moderna bivalent Original/Omicron vaccine)*
- Allergic reaction such as hives (*Moderna bivalent Original/Omicron vaccine and less frequently in Pfizer BioNTech bivalent Original/Omicron vaccine where frequency was rare)*
- Enlarged lymph nodes
- Muscle spasms
- Excessive sweating including night sweats (*Pfizer BioNTech bivalent Original/Omicron vaccine*)
- Having trouble sleeping (*Pfizer BioNTech bivalent Original/Omicron vaccine*)

Rare side effects (may affect up to 1 in 1,000 people)

- One-sided facial drooping
- Swelling of the face
- Decreased sense of touch or sensation (*Moderna bivalent Original/Omicron vaccine and less frequently in Pfizer BioNTech bivalent Original/Omicron vaccine although the frequency is unknown)*
- Unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia) *(Moderna bivalent Original/Omicron vaccine and less frequently in Pfizer BioNTech bivalent Original/Omicron vaccine although the frequency is unknown)*

Very rare side effects (may affect 1 in 10,000 people)

- Inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations, or chest pain. Seek immediate attention should these occur.

Side effects where the frequency is unknown

- Severe allergic reactions with breathing difficulties (anaphylaxis)

- Reaction of increased sensitivity or intolerance by the immune system (hypersensitivity) *(Moderna bivalent Original/Omicron vaccine*)
- a skin reaction that causes red spots or patches on the skin that may look like a target or "bulls eye" with a dark red centre surrounded by paler red rings (erythema multiforme).
- Extensive swelling of the vaccinated limb
- Heavy menstrual bleeding, although most cases appeared to be non-serious and temporary in nature.

Participants on the study will have blood tests done to check on their safety and to monitor symptoms. If you begin to feel unwell and would like to speak to someone, please contact your hospital study team [INSERT HOSPITAL STUDY TEAM CONTACT DETAILS].

Other potential disadvantages

The potential impact of Evusheld on other medicinal products (including any COVID-19 vaccine) is not known. There is a possibility that receiving the study drug prior to vaccination may result in the COVID-19 vaccine being less effective up to nine months to one year or more or may cause the vaccine to have other currently unknown side effects. Studies thus far have indicated that it is unlikely that Evusheld will impact on the COVID-19 vaccines.

You will be asked to attend the clinic a total of **seven** times (including your baseline visit) throughout the study so that we can assess how you are and collect blood samples. This may increase your risk of contracting COVID infection. Your clinical care team will do their best to limit your exposure to potential infections during your time at the hospital visits.

Obtaining blood samples may sometimes cause pain at the site where the blood is drawn from bruising, occasional light-headedness, and fainting, which is relatively rare.

Are there things I will be asked to avoid doing during the trial?

Blood donation

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 preventive interventions for COVID-19.

COVID vaccines outside of the trial

Participation in this study means that, unless the study team specifically advise otherwise, you will not be able to receive any of the approved NHS COVID-19 vaccines for three months after receiving your booster vaccine on this study as this may affect the results of the study.

Pregnancy, contraception, and breast-feeding.

Because the effects of Evusheld on an unborn child or infant are not yet known, pregnant or breast feeding women are not eligible for the trial. If you are able to become pregnant you must be willing to practice continuous effective contraception during the study for up to three months following your dose of Evusheld. Your study doctor can discuss acceptable birth control methods with you. It is suggested, that male participants should use a condom from day 1 and continue through 3 months after receiving the study drug.

If you are male, by signing this consent form, you agree to avoid getting your partner pregnant and you agree not to donate sperm while you are in the study and for up to three months after the last dose of Evusheld.

If during the treatment period, or for up to three months after Evusheld, you learn that you are pregnant or your female partner becomes pregnant, you must tell your study doctor immediately. During your study visits, the study doctor may ask you for more information about any pregnancy to see if there are any effects of the study medication on unborn children. If you are male and report a pregnancy of your female partner, the study doctor will ask to speak to your partner, if she agrees to this.

What will happen to any samples I give?

As part of this study, you will be asked to provide blood samples on day 0, 28, 56, 112, 180, 273, 364.

The blood samples you provide will be analysed and reviewed by laboratories to see how your immune system has responded to the medication. Your samples will be analysed at laboratories based in Oxford University, Public Health England and PPD (USA). Samples may be released for further analysis to researchers from other universities or commercial companies. This may include research undertaken outside of the European Union. The samples will not have any of your personal information written on them but they may be linked back to your clinical data such as your age or medical history. Both your samples and clinical data will be identified by your unique study reference number only. To safeguard your rights, we will use the minimum personally identifiable information possible. Your samples will be stored in a secure building.

If you decide to stop taking part in this study, your personal information, and samples that we have already collected will still be used in the ways that you agreed to when you started in the study. Your samples/data that have already been collected will be used unless you explicitly request for them to be destroyed. You can discuss this with your study doctor. If requested, we will try to destroy your samples.

Oxford Vaccine Centre Biobank

Varley M, *et al. BMJ Open* 2025; 15:e084345. doi: 10.1136/bmjopen-2024-084345

Some of your samples may be left over following this research. We will ask you if they can be stored in the Oxford Vaccine Centre Biobank and used for future research. The Oxford Vaccine Centre Biobank is a library of stored biological samples. These samples are used for further research on immunisation, immunity, and infectious diseases and may include DNA analysis. There is a separate information sheet and consent form for this aspect of the study. Your decision on whether to consent to samples being stored at the Oxford Biobank will have no impact on your participation in the main RAPID-PROTECTION study. Upon your request at any time, your remaining blood samples will be destroyed but if the samples are no longer linked to you, this might not be possible.

What will happen to the results of the research study?

The results of this research will be presented at national and international meetings and then published in high impact journals. You will not be mentioned in a way that would let people find out who you are.

At the end of the RAPID-PROTECTION study, a lay summary of the results of this study will be sent to the doctors at the participating hospitals and they will be asked to explain the results to the patients involved.

We will share the results of your 28 day and 6 month antibody test via a participant results letter. We cannot guarantee the timing of when these results will be shared after your 28 day and 6 month appointment as it will be dependent on the lab turnaround time. Vaccines typically work by stimulating the body to create antibodies. Evusheld offers a different type of protection which does not rely on the immune system. It is important to note that we do not yet know how different antibody levels relate to the level of protection against COVID-19 provided by Evusheld and the booster. RAPID- PROTECTION is a research study, your doctor and trial team are unable to provide medical advice regarding your results or make any recommendations around decisions or behaviour. You should still follow the current COVID-19 government advice.

Will I be compensated for taking part?

Once enrolled you will be compensated for your time, the inconvenience of having blood tests and procedures, and your travel expenses. The amount compensated will be £30 per visit, with a total of £210 per patient for participating in this study.

Your hospital study team will invoice the Centre for Trials Research (CTR) at Cardiff University for your study visits, CTR will send payments to your hospital site and they will be responsible for passing this payment on to you.

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What happens if I do not want to take part or if I change my mind?

Taking part in the study is entirely voluntary. If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. For us to understand and respect your decision, you will be asked to complete and sign the 'RAPID-PROTECTION Withdrawal of Consent Form'.

If you wish to stop taking part in the study, your standard of care will not be affected. The information we have recorded about you and the samples you have provided whilst you were on the study may still be used. You can ask for your samples to be destroyed, but please consider how valuable these are to our research before making a decision. Please note, we are not able to delete data collected prior to withdrawal due to the need to retain it to ensure the validity of research. However, we are able to restrict the use of this data in any subsequent analysis and publication. In some circumstances, it will not be possible to restrict the use of your data or destroy samples, for example, if the analysis has already been conducted, or if reports/publications have been written, or if we are unable to identify your samples/data after they have been anonymised.

What if new information becomes available?

Sometimes over the course of a research study, new information becomes available. If this happens, your study doctor will tell you about it as soon as reasonably possible and discuss whether you should continue in the study.

These are new medications, and there may be side effects that we are not yet aware of. Further information about safety is being actively gathered as the vaccines and Evusheld are being used globally. You will be informed of any significant change in the vaccine safety profile by your trial doctor.

Data Protection and Confidentiality

This section goes into detail about how we use and protect your data. It also describes options for you to maximise your contribution to research by sharing the data from this trial with other organisations for future research.

What information will you collect about me and how will it be used?

To get the answers we need from the research described in this document, we must collect personal information about you and your health. This includes information collected at your hospital during this study and information that is already in your medical records. As well as information about your health and the results from the tests and examinations mentioned previously, we need information such as your month and year of birth, gender, race and

initials. Once enrolled on the study, you will be assigned a unique trial number which will be used, in addition to your partial date of birth (mm/yyyy), throughout your participation in the trial to link your trial data.

Some of your information will be shared with the laboratories looking at your samples, and with the collaborating partners who are organising and funding this research work. Data will be used to learn more about Evusheld and COVID-19. It may also be used to answer other questions including safety of Evusheld. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

You can ask your study doctor to see the information that has been collected about you. If you think any of it is wrong, you can ask your study doctor in writing if it can be changed or removed.

You can find out more about how we use your information https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection.

Sharing your data outside of the study

Since you will receive a COVID-19 vaccine booster as part of the study, we will update your vaccine status in national vaccine databases such as the National Immunisation and Vaccine System (NIVS) and/or NHSX records.

With your consent, other researchers may use the results from this study to find out more about Evusheld, COVID-19 vaccines and immunosuppression. They may do this for example by combining the results from this study with results from other studies or by doing additional analysis on the samples that you have provided. If Cardiff University shares your information, Cardiff University will make sure that they cannot find out who you are and that such research is in line with this document. The information will only be used for the purpose of health and care research in accordance with the UK Policy Framework for Health and Social Care Research. The information cannot be used to contact you nor will it affect your care. Researchers may be based in universities, NHS organisations or companies involved in health and care research in this country or abroad. All information about you will be handled in strict confidence.

Providing permission for sharing your data outside of this study is optional and will not affect your participation in the study in any way. You will have the option to limit your data being shared outside of the study should you wish to change your mind.

Taking part in future vaccine-related research

With your consent, we would like to keep your contact details after the study is complete, so we may inform you of opportunities to participate in future COVID-19-related research. This

is entirely optional and will not affect your participation in this study. If you consent to be contacted in the future, we will collect your contact details such as your name, email address and telephone number. Your details will be stored electronically on a secure server and only authorised individuals at the Centre for Trials Research (CTR) at Cardiff University 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.

Linking your data with your health records

With your permission, information from this study may be linked with other sources of healthcare data in the future, including NHS Digital/Digital Health and Care Wales. If you consent to this part of the study, information such as your name and your NHS number will be used to identify your health records. Conducting research in this manner may help us understand the broader impact of COVID-19 on patients with immunosuppression. Where we share your data with NHS Digital, we will seek to share the minimum amount necessary (please see NHS Digital's privacy notice for how it uses your data).

Under what legal basis are you collecting this information?

In accordance with data protection law, Cardiff University is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential, and used only in the way you have been told it will be used. All researchers are trained with this in mind.

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protects your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes."

Will my participation in the study be confidential and my personal identifiable information be protected?

Individuals from the CTR at Cardiff University, Oxford University Hospitals NHS Foundation Trust or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant. We will follow ethical and legal practice and all information about you will be handled in strict confidence. Once the study is completed, your NHS site, CTR/Cardiff University and Oxford University Hospitals NHS Foundation Trust

will keep the research data for 25 years after the study has finished. The need to store this information for longer will be subject to ongoing review, taking into account the value of retaining this information for participant safety (e.g. to inform participants of unexpected safety signals emerging from post-licensing surveillance), as a resource for the participants (e.g. if they wish to check which vaccines they have received in the study) and any regulatory requirements. 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.

Who has reviewed the research project?

The study has also been reviewed by two independent lay members known as Public and Patient Involvement (PPI) members who have been included in the review of the study and all patient facing documents.

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Fulham Research Ethics Committee (Reference number 22/HRA/0359). The project has also been reviewed by the Health Research Authority (HRA) and Medicines and Healthcare products Regulatory Agency (MHRA).

Who will conduct the research?

The study is being organised by the Centre for Trials Research in Cardiff University on behalf of the Chief Investigator, Dr Mark Tuthill, who is based at the Oxford University Hospitals NHS Foundation Trust. Cardiff University is acting as the Sponsor responsible for the study.

Who is funding the research project?

The study has been funded by the Pharmaceutical Company, AstraZeneca.

What if I have a complaint?

If you have a concern about any aspect of this study, you should contact the researchers who will do their best to answer your questions at Rapid-protection@Cardiff.ac.uk. If you remain unhappy and wish to complain formally, you can do this by contacting a NHS complaints advocate. Details can be obtained from https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/]

In the event that something does go wrong, and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for

Varley M, *et al. BMJ Open* 2025; 15:e084345. doi: 10.1136/bmjopen-2024-084345

compensation against Cardiff University but you may have to pay your legal costs. Cardiff University will provide compensation for any injury caused by taking part in this study. Cardiff University will pay compensation where the injury probably resulted from:

- A drug being tested or administered as part of the trial protocol;
- Any test or procedure you received as part of the trial.

Any payment would be without legal commitment (please ask if you wish more information on this). Cardiff University would not be bound by these guidelines to pay compensation where the injury resulted from a drug or procedure outside the trial protocol or where the protocol wasn't followed. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Contact Details and further supporting information

If you have any questions or would like further information about the study please contact your hospital study team: [INSERT HOSPITAL STUDY TEAM CONTACT DETAILS].

To access the most recent EVUSHELD Fact Sheets, visit http://www.evusheld.com

For more information about the trial, visit https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/rapid-protection

To learn more about COVID-19 visit https://www.cdc.gov/COVID19

Thank you for reading this information and considering taking part in this study.

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Please print on local hospital headed paper

RAPID-PROTECTION: an adaptive clinical trial of Evusheld and COVID-19 vaccination in immunosuppressed patients highly vulnerable to infection with COVID-19 virus

Participant Consent Form

Version:	V4.0
Date:	13/01/23
ISRCTN	ISRCTN53507177
EudraCT:	2021-006703-15
Sponsor:	Cardiff University
Sponsor No:	SPON1884-21
Trial No:	
IRAS ID:	1004764

Site Number:

Participant Trial Number: | | | | | | |

Name of Principal Investigator: | |

If you would like to take part in this study, please complete this consent form by **initialling** the boxes and signing below. **Boxes 1-10 must be initialled for consent to be valid.**

1.	I confirm that I have read the Participant Information Sheet (V4.0, 13/01/2023) for the above study and have had the opportunity to consider the information and ask questions and had these answered satisfactorily.	
2.	I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to myself. I understand that it will not be possible to remove my data from the project once it has been anonymised and forms part of the data set. I agree to take part on this basis.	
3.	I agree to have blood samples taken for the research purpose as explained to me.	
4.	I agree for my medical records to be accessed by the NHS Trust that is delivering the study (which may be different to my local NHS Trust that is responsible for my healthcare outside of this study). Your medical records may be reviewed by individuals from The Centre for Trials Research (CTR) at Cardiff University for monitoring purposes.	
5.	I understand that data and samples collected during the study may be looked at by individuals from The Centre for Trials Research (CTR) at Cardiff University, Oxford University NHS Trust, AstraZeneca, and the Laboratories at PPD and Oxford University, Public Health England, or regulatory authorities, where it is relevant to my taking part in this research. Other analysis may be done by collaborating laboratories in the UK and in other countries including North America. I give permission for these individuals to have access to my samples and data.	
6.	I understand that by taking part on this study, I agree not to receive additional COVID vaccine boosters outside of this study as stated within this document.	
7.	I agree that any data collected may be published in anonymous form in academic books, reports, or journals.	
8.	I agree to use contraception methods approved by my doctor if and where required.	
9.	I agree to inform the Doctor, Research Nurse and Centre for Trials Research if my partner or I become pregnant whilst taking part in the study.	
10.	I agree that my General Practitioner will be informed of my participation in this study and will be advised of any clinically significant information that comes to light.	
11.	I understand that the NHS Trust delivering the study is not responsible for any care and treatment that I may be receiving outside of the study.	
12.	I agree to take part in this study.	

The below are optional statements:		Initial each box
I agree to my samples being stored indefinitely at the study approved Biobanks for future research by researchers from other universities or commercial companies, and that this may include researchers working outside of the United Kingdom. I give permission for these individuals to have access to my sample (including DNA).	☐ YES ☐ NO	
I agree for my clinical and laboratory data to be used for future studies undertaken by researchers from other universities or commercial companies, and that this may include researchers working outside of the United Kingdom. I understand that the data shared will not directly identify me.	☐ YES ☐ NO	
I agree for my personal identifiers to be used to link study data to sources of health information on applicable databases including NHS digital/Digital Health and Care Wales, and for the anonymised data to be used by researchers involved in the Rapid Protection study.	☐ YES ☐ NO	
I agree to provide my contact details so that I may be contacted in the future by the study team in relation to other research studies.	☐ YES ☐ NO	

Patient: I consent to the above initialled points.		
Name of Participant	**Date**	**Signature**
……	……	……

Person taking consent: I confirm that I have explained the nature of the RAPID-PROTECTION trial and the optional data use within the study to the above named patient and that s/he has understood the explanation given to him/her. *(Sign if different from Principal Investigator. If signatory is not a medically qualified person, the Principal Investigator must counter-sign below).*		
Name of person taking consent	**Date**	**Signature**
……	……	……
Principal Investigator: *(Must be signed by Principal Investigator if consent was taken by a member of staff who is not medically qualified).*		
Name of Principal Investigator	**Date**	**Signature**
……	……	……

Patient identification number for this trial: ……..

Copies: 1 for patient, 1 for researcher to be stored in the trial site file, 1 to be kept with hospital notes