Title of Project: Understanding the role of inhaled corticosteroids (ICS) on vascular ageing and cardiovascular comorbidities in COPD

Chief Investigator: Dr Koralia Paschalaki

Invitation:

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and discuss it with others if you'd like. One of our team will go through the information with you and answer any questions you have. This should take about 15 minutes. If anything isn't clear, or if you'd like more details, just ask. Take your time to decide whether you wish to participate.

What is the purpose of the study?

Patients with chronic obstructive pulmonary disease (COPD) often have not only breathing problems but also heart and blood vessel diseases, known as cardiovascular disease. Cardiovascular disease is a leading cause of death in COPD patients. Recent large studies show that patients with COPD who use inhaled corticosteroids (ICS) have a lower risk of dying, mainly due to fewer heart-related events. However, we don't fully understand how ICS treatment helps prevent heart problems in these patients.

The cells that line the blood vessels, called endothelial cells, play an important role in keeping your heart and blood vessels healthy. As these cells age, they don't work as well, which can lead to heart disease. There are also special cells in your blood, known as Endothelial Colony Forming Cells (ECFC) that help repair damaged blood vessels. We have found that in people with COPD, these cells don't work as well and age faster. However, patients who are treated with ICS have healthier, younger cells that can better repair blood vessels.

This study aims to find out if ICS treatment slows down the ageing of these cells and improves their ability to protect blood vessels. This could help prevent heart disease in patients with COPD.

Why have I been chosen?

We are asking you to take part in this study because you have COPD and you have not been on regular ICS treatment. We are looking for 60 volunteers with COPD for this study.

Do I have to take part?

No, it's entirely your choice. If you decide to take part, you'll be given this information sheet to keep, and you'll be asked to sign a consent form. You can change your mind and stop participating at any time, without giving a reason. This will not affect the care you receive.

What will happen to me if I take part?

This study is a Randomised Trial. This means we're comparing different treatments to see which one works best. A computer will randomly assign participants to one of two groups, and each group

will receive a different treatment. This helps us make fair comparisons between the treatments. The research team will not know which treatment you're getting**.**

Below we will describe what procedures and tests we will do if you agree to take part in this study. These are standard hospital tests, but you would not normally undergo all of them as part of routine care for your COPD. The study will last for 12 weeks, and during this time, you'll need to visit the *Respiratory Research Centre at the Royal Brompton Hospital* two or three times.

Here's what will happen if you agree to take part:

Screening visit

You'll need to come in for a screening visit to check if you're suitable for the study. During this visit, we will:

1. Answer any questions you may have and confirm if you're willing to participate by signing a consent form.
2. Discuss your medical history.
3. Perform a basic physical exam, including checking your blood pressure, heart rate, and listening to your heart and lungs.
4. Do a lung function test (spirometry) if it hasn't been done before, and an electrocardiogram.
5. Perform an electrocardiogram.
6. Ask you to complete a questionnaire about your breathing symptoms.

These tests will help us determine if you are suitable for the study and assess how severe your lung condition is. If you are suitable, we will invite you to come back for the main study visit.

Because the inhalers we are testing may affect pregnant and breastfeeding women, women of childbearing age who attend the screening visit will also have to share details of their current contraceptive methods. The following methods will be deemed effective by the study team:

1. combined, or progestogen only pill
2. intrauterine device (IUD) (copper coil),
3. intrauterine system (IUS) (hormonal coil),
4. contraceptive implant,
5. contraceptive injection,
6. contraceptive patch,
7. vaginal ring,
8. condoms or internal condoms,
9. female sterilization and vasectomy (of the male partner).
10. sexual abstinence (a highly effective method only if defined as refraining from heterosexual intercourse during the entire period of risk associated with the study treatments. The reliability of sexual abstinence needs to be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the subject." in line with the Clinical Trials Coordination Group guidance).

Once you have attended the screening and been enrolled into the study, we will write a letter to your GP informing them of your study participation and provide them information about the study. You may also discuss your participation with your GP if you wish.

First visit (may be combined with screening visit)

The main study visit will consist of the following tests, explained in detail below:

i) a lung function test (spirometry),
ii) perform a simple exercise test,
iii) complete some questionnaires regarding your breathing symptoms
iv) measure your blood pressure, height and weight,
v) perform a non-invasive test to assess the health of your blood vessels
vi) collect a blood sample.

The screening and study visits (two visits) can be combined to one if you wish so, and the whole procedure will take less than 4 hours. However, we might find that you are not a suitable candidate for the study after the screening visit. In such case, we will not ask you to participate in the main study visit.

At the end of the study visit 1 you will collect your medication from the pharmacy at the Royal Brompton Hospital.

You will be scheduled for a second visit in 12 weeks.

Telephone call during the course of the study

At weeks 4 and 8 of your treatment, we will contact you by phone to ask about any events related to your health that may have taken place. This should take approximately 5-10 minutes.

Second visit (final visit)

Before you attend the clinic, you will first visit the pharmacy who will collect the medication (all empty inhalers and devices with remaining doses).

We will then perform the same investigations as in the first visit:

i) a lung function test (spirometry),
ii) perform a simple exercise test,
iii) complete some questionnaires regarding your breathing symptoms,
iv) measure your blood pressure, height and weight,
v) perform a non-invasive test to assess the health of your blood vessels
vi) collect a blood sample.

Please see below the details of the **tests included in this study**:

Spirometry is a type of lung function test that involves breathing out hard into a mouthpiece. It measures the amount of air that you can exhale in one second as well as the total volume that you exhale.

Reversibility: After the spirometry test, we will ask you to inhale a medicine called salbutamol (a drug that opens up the airways and is routinely used in patients with asthma). We then wait for 15 minutes and repeat the test.

Exercise test

We want to see how far you can walk in six minutes and will measure the distance you can cover in this time.

Questionnaires

We will ask you to complete the following questionnaires:
MRC dyspnoea scale is a scale in which words describe levels of breathlessness (shortness of breath) on a scale of 0 and 5. You will be asked to select a number which closely describes your level of breathlessness.
COPD Assessment Test (CAT): This questionnaire assesses all aspects of COPD and how it impacts you (cough, sputum, breathlessness, chest tightness, confidence, activity, sleep and energy levels). There are 8 questions on a 1-to-5-point scale. You need to tick the one that best represents the severity of your symptoms.
St. George's Respiratory Questionnaire (SGRQ): the best-known and most used disease-specific quality of life (HRQL) questionnaire for respiratory diseases. The SGRQ is a standardised, questionnaire for measuring reduced health and quality of life in people with lung diseases. It contains 50 questions, divided into three sections (Symptoms, Activity and Impacts). A score is calculated for each section and a total score, including all questions is also calculated.

Endothelial dysfunction measurements (EndoPAT)

We want to measure the rate of blood flow in your vessels, and we will do that by a non-invasive method named endothelial pulsatile arterial tone (EndoPAT).

We will ask you to sit comfortably on an armchair or lay on your back for 10 minutes to relax. We will measure your blood pressure (BP) throughout the study visit.

EndoPAT: We will place two specially designed sensor probes, on either your index or middle fingers. These probes contain a system of inflatable latex air cuffs connected by tubes to a device controlled through a computer. We will measure the arterial tone signal from your fingertips We will record your resting signal for 5 minutes. We will then use a blood pressure cuff on the test arm, which will be inflated to 60 mm Hg above the baseline of the systolic BP or at least to 200 mm Hg. After 5 minutes, the cuff will be deflated, and we will record the signal for 5 more minutes.

Picture of the EndoPATX device that will be used in the study.

Blood sampling: We will then take a blood sample from your arm, of about four to five tablespoons (80ml). This is the amount of blood we need to measure the different types of cells in your blood. This includes several inflammatory biomarkers, lipids and other biomarkers related to heart disease. We will also isolate a fraction of cells from your blood (mononuclear cells) to be able to isolate and grow endothelial cells (ECFC) in the laboratory.

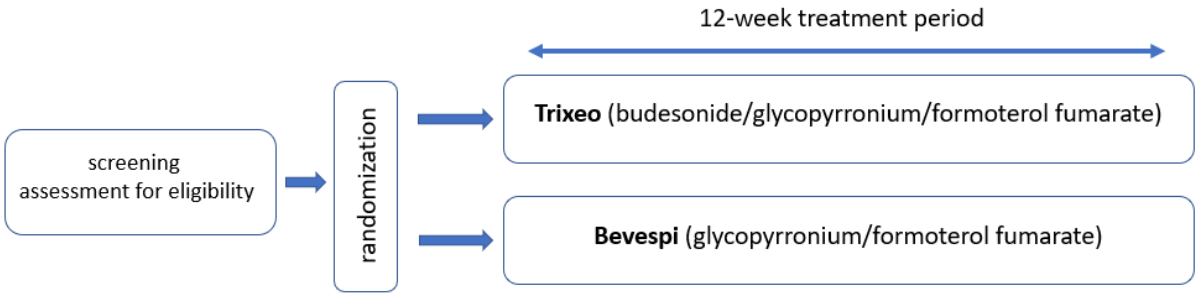
Only your samples that go to the NHS lab for routine measurements will be labelled with your details. None of your samples handled in our research lab will be labelled with your name but will be coded with letters and numbers (will be pseudonymised). You will not be identified in any reporting of results.

This research study does not involve genetic testing for family diseases, but we will take samples of your DNA to see if it has been chemically modified. However, we will separate your DNA and RNA to see if different genes are switched on in COPD and maybe switched off with treatment. No testing for serious disease (especially HIV and Hepatitis B) will be performed. As samples of your DNA have been taken there is a potential that data may be traced back to you. At the end of the study, if any of your samples remain and you consent to this, they will be kept for future experiments approved by a National Research Ethics Committee, but you will not be contacted further.

Any data or samples collected during this study will be pseudonymised and will be used by Imperial College London. The data will be identified by a unique code and will not have your name or any information that specifically identifies you.

If you do not wish for your tissue samples to be kept for further studies and shared by Imperial College after the study has stopped these will be destroyed.

Participant flow diagram



Screening Visit (2-3h in clinic)
i. Consent to study
ii. Medical history
iii. Height, weight, blood pressure, ECG
iv. Lung function (Spirometry)
v. Questionnaire about symptoms

Visit 1 (1-2h in clinic)
i. Lung Function (Spirometry)
ii. Exercise test
iii. Blood pressure, height, weight
iv. Questionnaires about symptoms
v. Measurement of endothelial function (EndoPAT)
vi. Blood test
vii. Training on inhalers
viii. Collect inhalers from pharmacy

Telephone call at 4 and 8 weeks (5-10 minutes)
i. Discuss medication use and any side effects

Visit 2 (1-2h in clinic)
i. Return all inhalers to pharmacy (used and unused)
ii. Lung Function (Spirometry)
iii. Exercise test
iv. Blood pressure, height, weight
v. Questionnaires about symptoms
vi. Measurement of endothelial function (EndoPAT)
vii. Blood test

Expenses and payments

All study medication will be provided to you at no cost. Your travel expenses to the Hospital will be reimbursed.

What do I have to do?

We will ask you to come for a screening visit and one study visit, which can be combined to one visit if you wish so, as detailed above.

We will ask you to fast for at least 4 hours before the study visit 1 and 2 only. We will also ask you to refrain from caffeine, tobacco, vitamins or medications that affect blood vessel tone for 8 hours, unless it is unsafe.

There are some medications that affect blood vessel tone such as bronchodilators (inhalers that open your airways) and blood pressure treatment. If you take these medications we will ask you to not take them for 8 hours before you come in for study visit 1 and 2. Stopping these medications for a short period (maximum 8 hours) is safe and not normally associated with any problems.You will need to take your medication once you finish the measurements, then resume taking them as usual. In the unlikely case you feel unwell after stopping your medication for this short time, you must take your medication immediately and contact Dr Koralia Paschalaki on 02075942728 or email: k.paschalaki@imperial.ac.uk. To discuss your symptoms, receive medical advice in case your participation will be postponed.

What is the drug that is being tested?

You will either receive a) an inhaler called ***Bevespi Aerosphere***, this is a blend of two drugs (glycopyrrolate, an anticholinergic, and formoterol fumarate, a long-acting beta2-adrenergic agonist (LABA)) that relax and open the airways, or you may receive b) ***Trixeo Aerosphere***, which has the same drugs as Bevespi plus budesonide, an inhaled corticosteroid. Both are metered-dose inhalers, providing you a dose of your medicine as an inhaled mist. Both treatments have been approved and are regularly used as treatment in patients with COPD.

Please ensure you tell the researcher if you are taking or have recently taken any other medication/ supplements/herbal therapies or if you have been involved in other drug studies. This is because contact between medicines (i.e. drug - drug interactions) can occur. This happens when the trial medication allocated to you may affect the way other drugs work, and some drugs can have an effect on the trial medication.

You should not take Trixeo or Bevespi Aerosphere with other anticholinergic and/or long-acting β_2-adrenergic agonist containing inhalers, as it may lead to adverse reactions.

You should also be cautious when receiving treatment with methylxanthine derivatives, steroids, or non-potassium-sparing diuretics, or any medicinal products known to prolong the QTc interval.

The metabolism of budesonide (included in Trixeo) is primarily mediated by CYP3A4. Co-treatment with strong CYP3A inhibitors, e.g. itraconazole, ketoconazole, HIV protease inhibitors and cobicistat-containing products, could increase the risk of side effects. These should be avoided unless the benefit outweighs the increased risk of reactions. In this case you should be under close monitoring, and we can discuss this with your GP or healthcare professional. This is of limited clinical importance for short-term (1-2 weeks) treatment.

Throughout the course of treatment, you will be asked to take your medication regularly. Your treatment regime will be two inhalations to be taken twice daily (morning and evening) for a total duration of 12 weeks. Do not take your medicine more often than directed. If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, take only that one, and skip your missed dose. Do not take extra or double doses. Tell your doctor straight away if you have taken more than your prescribed dose.

You will be given a card (like a credit card) with details of the study which we advise you carry at all times.

Because the study inhalers may interact with other medications you may be on, we have provided a list below of the types of medications that you are unable to take during the study. If you are on any of these, you will not be able to take part. If you are on any of these medications but wish to participate, you will have to discuss this with your GP or the healthcare professional who prescribes your medications before enrolling into the study.

Prohibited Medications
Class of Medication
• Any drug with potential to significantly prolong the QT interval • Other investigational drugs • Non-selective β-blocking agents (Except Carvedilol) • Cardiac antiarrhythmics Class Ia, III (amiodarone) • Anticonvulsants • Tricyclic antidepressant • Monoamine oxidase inhibitors • Anti-tumor necrosis factor α antibodies (eg, infliximab) • Monoclonal antibodies • Antipsychotic drugs • Systemic calcineurin inhibitors, protease inhibitors • Systemic anticholinergics • Antiplatelet treatment • Systemic treatment with strong CYP3A4-inhibitors (e.g., ketoconazole, itraconazole, and ritonavir) • HIV protease inhibitors • Live attenuated vaccines (emergent vaccines before or during the study need to be discussed at study level.)

What are the alternatives for diagnosis or treatment?

There are alternative drugs (for example other inhaled bronchodilators, steroids) used for COPD patients. You are free to decide to be treated with one of these instead of participating in the study. Such a refusal in no way will affect the way you are seen and treated by your doctor. If you decide to participate, you will be allowed to continue with your current medication, provided it does not interact with the drugs used in this trial.

What are the side effects of any treatment received when taking part?

Both drugs are regularly prescribed in COPD and have been proven to be safe and effective overall. However, as with all medicines, there may be some unwanted side effects. The common, uncommon, and very rare side effects are listed below in tables.

Please stop taking the medication and get medication help immediately if you experience any of the below side effects as these may be a sign of an allergic reaction that may become serious.

Serious side effects	**Frequency**
Swelling of the face, mouth, throat Rash or hives Feeling faint/ dizzy Immediate breathing difficulties	Uncommon may affect 1 in 100 people

Please contact us and your GP if you experience any of the common side effects.

Table of other side effects

Side effect	Frequency
• thrush in the mouth (a fungal infection). Rinsing your mouth out with water immediately after using the medication to prevent this. • feeling anxious • difficulty sleeping • feeling sick (nausea) • headache • coughing or a hoarse voice • muscle cramps • awareness of your heart beating (palpitations) • high blood sugar levels (as shown in tests) • painful and frequent urination (may be signs of a urinary tract infection) • pneumonia (infection of the lung)	*Common* may affect 1 in 10 people
• shaking or tremor • agitation • feeling restless • fast or irregular heartbeat • difficulty passing urine (urinary retention) • bruising of the skin • chest pain (angina)	*Uncommon* may affect 1 in 100 people
• changes in behaviour • An effect on the adrenal gland	*Very rare* may affect 1 in 10,000 people

There may also be other side effects that we cannot predict.

What are the possible disadvantages and risks of taking part?

We do not expect any harmful effects from the study procedures.

There is a risk of a small bruise from blood sampling and a small risk of fainting in a few participants.

Some of the breathing tests may leave you feeling breathless. If this happens, we will ask you to use a medicine called salbutamol that is given routinely to patients with asthma. This will open your airways and allow you to breathe more easily. You should not hesitate to report any other side effects which may be unpleasant.

There might be some discomfort from the inflated blood pressure cuff during the measurement of endothelial dysfunction. If you find this too uncomfortable the blood pressure cuff will be deflated.

All the procedures are well established and used on a routine basis.

It is possible that if the treatment is given to a pregnant woman, it will harm the unborn child. Pregnant women must not therefore be able to take part in this study, neither should women who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part, to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during this study as described on page 2. Any woman who finds that she has become pregnant while taking part in the study should immediately tell her research doctor.
Patients who are breastfeeding will not be able to participate in the trial as Budesonide passes into breast milk. It is unknown if glycopyrrolate or formoterol passes into breast milk.

What are the possible benefits of taking part?

We cannot promise the study will help you, but the information we get might help improve the treatment of people with COPD.

Some patients may benefit from the increased contact with the hospital and welcome the opportunity of discussing their lung problems with the research staff and doctors. If you are a smoker, should you wish to quit smoking, the study doctors can refer you to the Royal Brompton Hospital smoking cessation clinic where you will be offered appropriate support.

Should the doctors find anything unexpected, they will discuss their findings with you and with your consent refer you to your GP or the appropriate clinic. Also, on receiving new information, your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

What happens when the research study stops?

At the end of the study, your GP will be notified, and you will return to the care of your primary care physician.

Once this study has been published, you may be able to find out which treatment you received. If you wish to find this out, you should ask your doctor to keep you informed. In case study treatment helped your lung disease, you can discuss with your doctor for the possibility of continuation of the treatment.

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury because you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about the way you have been treated during the course of this study then you should immediately inform the lead investigator (Dr Koralia Paschalaki: k.paschalaki@imperial.ac.uk 02075942728).

The normal National Health Service mechanisms are also available to you and you can contact the Patient Liaison Service (PALS) at the Royal Brompton Hospital via telephone 020 7188 3514, or email pals@rbht.nhs.uk. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team

Will my taking part in this study be kept confidential?

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study is expected to finish in February 2026 for more information / confirmation regarding the end date please contact the study team, see '**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact information.

We will need to use information from you and from your medical records for this research project. This information will include your

- Initials
- NHS number
- name
- contact details

People within the College and study team (see section sharing your information with others) will use this information to do the research. To check your records, to make sure that the research is being done properly and the information held (such as contact) details are accurate.

People who do not need to know who you are, will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you in a safe and secure location

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

LEGAL BASIS

As a university we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - "performance of a task carried out in the public interest"); Health and care research should serve the public interest, which means that we must demonstrate that our research serves the interests of society. We do this by following the UK Policy Framework for Health and Social Care Research

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London relies on "scientific or historical research purposes or statistical purposes.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third-party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies. This could be both at Imperial College London and in other universities or research organisations in the UK and abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

COMMERCIALISATION

Samples or data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations. For the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name, and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample / data analysis having the potential to generate ‘personal data’.
Combined or anonymised data sets (all identifying information is removed). May also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes, where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. This is because some research using your data may have already taken place and this cannot be undone.

- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital and your GP. If you do not want this to happen, tell us and we will stop. This will not affect any healthcare or support you may be receiving separately
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you, if this could affect the wider study or the accuracy of data collected.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to k.paschalaki@imperial.ac.uk, or
- by ringing us on 02075942728.

COMPLAINT

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to k.paschalaki@imperial.ac.uk, or by ringing us 02075942728.

Following our response, if you are not satisfied, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful, you can complain to the Information Commissioner's Office (ICO) via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

What will happen to the results of the research study?

The results from the study may be published in a medical journal, but your identity will not be revealed. We would also like to use the information for:

- Administration purposes
- Statistical analysis

As a result of the samples being pseudonymised, any contribution of your sample to the overall results of the study cannot be identified. However, in signing this form, you do not give up any other rights that you would have as a participant in research

The study doctor will be able to tell you where the results are published when the study is finished.

Who is organising and funding the research?

The study has been organised by the National Heart and Lung Institute which is a part of Imperial College London who are the sponsor of this study. The study will be funded AstraZeneca.

Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by xxxx REC.

Contact for Further Information

If you have any further questions about this study, please contact our research team on the following 24-hour contact details:

Dr Koralia Paschalaki

Tel: 02075942728

Email: k.paschalaki@imperial.ac.uk

You will be given a copy of this information sheet and the signed Informed Consent form to keep.

Thank you for taking the time to read this information sheet and taking part in this study!