Imperial College London

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PATIENT INFORMATION SHEET

C-19-ACS

Preventing Cardiac Complications of COVID-19 Disease with Early Acute Coronary Syndrome Therapy: A Randomised Controlled Trial

Chief Investigator: Professor Prapa Kanagaratnam
Study Sponsor: Imperial College London
Sponsor Number: 20HH5868
Co-ordinating site: Charing Cross Hospital
PIS Version number: Version 3.0, 29/09/2020
IRAS number: 281827

You are invited to participate in a research study investigating treatment of COVID-19 disease. Please take your time to read and consider the information given in this information sheet carefully. In making your decision, make sure you allow enough time to reflect on the information read. Thank you.

WHAT IS THE PURPOSE OF THIS STUDY?

The outbreak of a novel coronavirus and associated COVID-19 disease in late December 2019 has led to a global pandemic. At the time of writing this information sheet there have been over 3,400,000 confirmed cases worldwide.

Most people will only suffer mild flu-like symptoms. A few will develop breathing problems and need to be looked after in hospital where they will be given oxygen, fluids and other therapy.

We have learnt from doctors in China and Italy that people with heart problems, diabetes or hypertension can be severely affected by COVID-19.

The purpose of this study is to find out whether giving tablets that are more commonly used for sudden heart conditions could help people with COVID-19 to cope better with the infection. These tablets are commonly used and are not new.

We do not know if these additional drugs will have any benefit or harm. To understand if there is any benefit or harm from the trial, half the people enrolled will receive the additional tablets and half will not. This will be done randomly and you will not be able to choose which half you are in. All patients will continue to receive the normal medical care. This will help us understand which treatment is better by comparing the two groups of people.

WHY WAS I INVITED?

You have been invited to take part in this study as you have been admitted to hospital with suspected COVID-19 infection. Your normal

medical team have agreed to give you the information sheet and discuss with you this trial of additional drugs. If they are able to answer your questions and you are willing to enrol they will ask you to consent to the study. If you are unsure or have more questions the research team can be contacted on the Study Mobile number 07776 224520 [+ *site contact number].* It is important that you and your family feel fully informed before you agree. Remember your normal care will continue and you are free to refuse to join the study or withdraw at any time, by informing your clinical team.

If you decide you would like to take part, then please read carefully and sign the Consent Form you have been given together with this Information Sheet.

WHAT DOES THE STUDY INVOLVE?

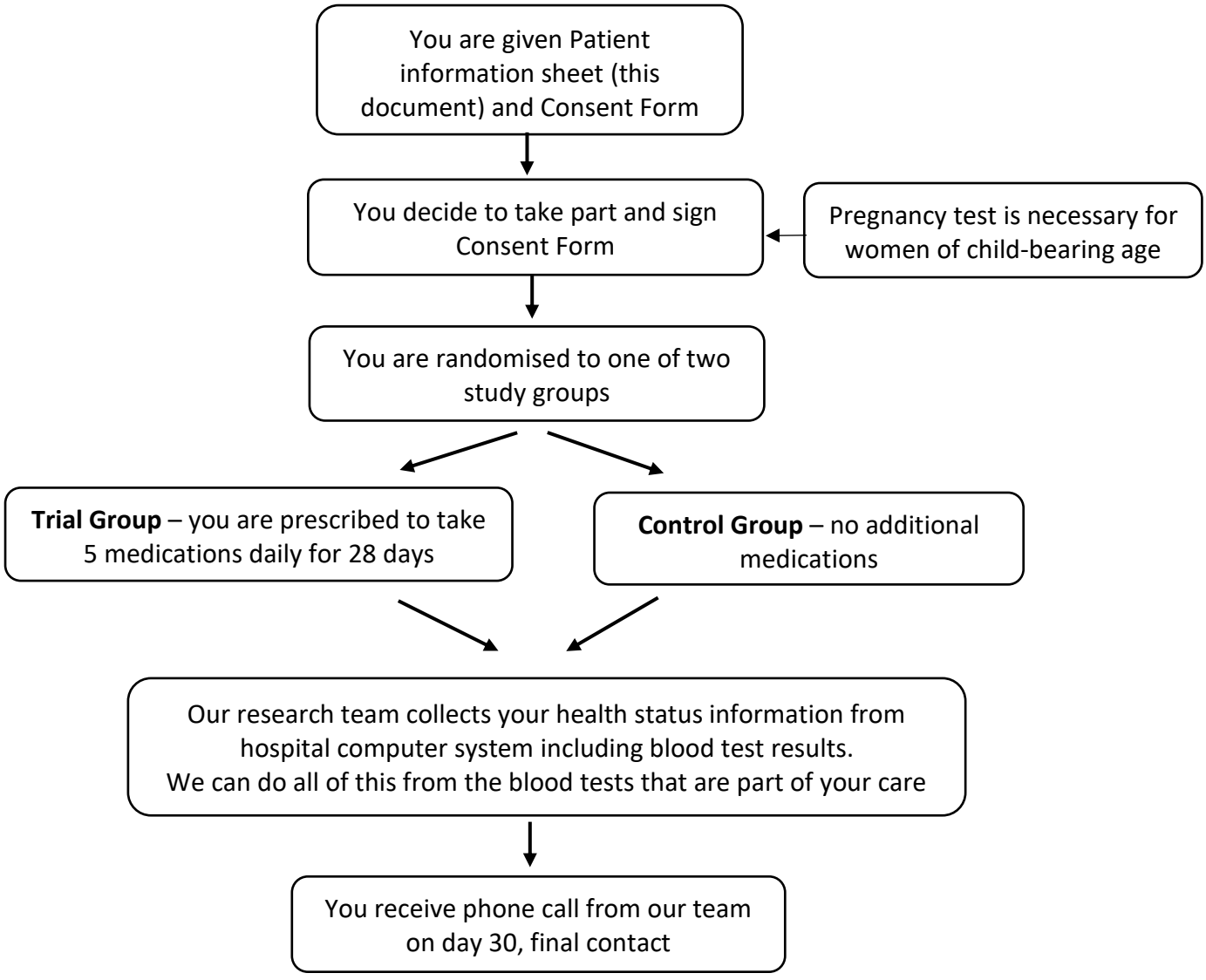
The study will have two groups of participants. One group will have additional medication to protect the heart prescribed by a member of the cardiology team (notifying your clinical team), another group will have no changes to the treatment they currently receive. If you have been randomised to the heart tablet group, the study involves you taking 5 medicines every day for 28 days. Both groups will receive a telephone call after 30 days, to discuss how you are feeling and any side-effects. This phone call marks the end of the study, no more data will be collected after this point.

The tablet medicines that will be prescribed to you if you are part of the trial group are:

- Drug1 (Aspirin) is a blood thinning medicine and helps to prevent heart attacks and strokes in people at high risk of them.
- Drug 2 (Clopidogrel) is an antiplatelet medicine, or blood thinner. It makes your blood flow through your arteries more easily. This means that your blood will be less likely to make a dangerous blood clot.
- Drug 3 (Rivaroxaban) is a type of medicine known as an anticoagulant, or blood thinner. It makes your blood flow through your arteries more easily. This means your blood will be less likely to make a dangerous blood clot.

- Drug 4 (Atorvastatin) belongs to a group of medicines called statins. It's used to lower cholesterol and is also taken to prevent heart disease, including heart attacks and strokes.
- Drug 5 (Omeprazole) is a stomach protection drug which reduces the amount of acid your stomach makes. It's a widely used treatment for indigestion and heartburn and acid reflux. It's also taken to prevent and treat stomach ulcers. Omeprazole can be replaced by Lansoprazole, another stomach protection drug, at the discretion of the treating clinician.

These medicines will be prescribed by your doctors or the Cardiology team, who will also keep track of your progress with help from the research team, and may adjust the medication.



If you leave the hospital before 30 days and you have been taking additional medications as part of this study, you will be given these medications to take home and continue to administer as in hospital, until day 28. We will call you on day 30 as a last follow up contact in any case, if you have been taking cardioprotective medication, or not. Your GP will be informed if you take part in this study.

At the end of the study, your care will continue in a routine manner.

The research team will have full access to the clinical notes and will use that data. Some information such as blood tests for indications of infection or any heart muscle strain (ie ferritin and troponin) are conducted routinely, but others such as follow up Troponin or pregnancy test will be in addition to the normal care.

WHAT ARE THE POSSIBLE RISKS?

If you are randomised to the control group, you face no additional risks by being involved in the study. Your care continues as it normally would were you admitted with COVID-19 disease.

If you are randomised to the trial group, there are risks associated with the side-effects of the different medications in this trial. If you experience any side-effects please tell your clinical team (if you are in hospital) or telephone the research team if at home.

Very common (approximately 1 in 10 participants)

1. Bleeding and bruising – this is common as Drugs 1,2 and 3 can cause bleeding as they all prevent the blood from clotting effectively. For example, mild bruising may occur when blood tests are taken or intra-venous lines inserted.
2. Indigestion- Drug 1 & 2 can cause mild indigestion. Drug 5 should prevent this from occurring.

Common (1 in 100)

1. Serious bleeding- this can happen as Drugs 1,2, and 3 can cause bleeding as they all prevent the blood from clotting effectively. This can usually be detected early and treated but can include blood in vomit or stool or feeling very tired or light-headed. If the treating

doctor needs the blood to clot normally or bleeding is severe these medications will be suspended. A blood transfusion may be advised if a lot of bleeding has occurred.

2. Liver or kidney impairment- Rarely, Drugs 1 & 2 & 4 can cause the liver or kidney to work less effectively. This will be monitored with blood tests and the medications stopped if there are any concerns. Usually these changes will be reversible and do not cause severe disease.
3. Aches in muscles and joints- Drug 4 can cause muscle aches in some people. These stop once the medication is stopped.

Rare (1 in1000 or less)

1. Anaphylactic allergic reaction- very rarely, patients can have a serious allergic reaction to any medication. This can be severe and result in death but can be treated if treatment is given in time. If the reaction is going to happen, they usually occur with the first dose which will be given in Hospital where you are closely monitored.
2. Muscle pain, tenderness, weakness or cramps- These can be serious and can occur with drug 4. They require blood tests to assess and monitor. The study medications would be stopped and these symptoms will resolve.
3. Skin rash (especially on palms of hands and feet), mouth ulcers- this is a very rare reaction to medications and can be very serious. The study medications would be stopped and you would need to stay in hospital for further treatment.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

The benefit of taking part in this study is to understand the management and improve outcomes for patients with COVID-19 infection. There may not be any direct benefit to you.

The study data will be analysed regularly to decide if the study should be extended to others or stopped.

WHAT IF I CHANGE MY MIND?

You can withdraw from the study at any point without giving a reason. Please let your clinical team know or contact the research team (number below). You do not need to give a reason.

Your clinical care team or research team may stop the medications at any time. They will notify you when and why if it is required.

If you decide to withdraw, it will not affect your further treatment or your rights in any way. It is important to note, that should you withdraw from the study, we will keep and continue to use all your previously collected data. We will not however collect any further data about you.

WHAT IF SOMETHING GOES WRONG?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, 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 any aspect of the way you have been treated during the course of this study then please phone our research team on the number listed at the end of this sheet. Alternatively, you can contact Patient Advice and Liaison Service (PALS):

Email: imperial.PALS@nhs.net

Phone: 020 3313 3322, Monday to Friday, 09.00-17.00

[*contact details of local PALs office*]

HOW WILL WE USE INFORMATION ABOUT YOU?

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.

We will need to use information from your medical records for this research project. This information will include your NHS number, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. 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 safe and secure.

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. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

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. 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.

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 [imperial.covidcardio@nhs.net [local research team email]

- by ringing us on 07776 224520 [*local research team phone number*]

USE OF YOUR PERSONAL DATA - COMPLAINT

If you wish to raise a complaint on how we have handled your personal data, 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. *[local Data Protection Officer contact details*]

If you are not satisfied 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). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

HOW WILL MY PERSONAL DATA BE KEPT CONFIDENTIAL?

All research members with access to the electronic medical records will record and store any study data by assigning you an individual study ID.

Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake 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 identifiable information about you 10 years after the study has finished in relation to primary research data. Further information on Imperial College London's retention periods may be found at: https://www.imperial.ac.uk/media/imperial- college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To

safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information by contacting the principle investigator or research team, their contact details are listed at the end of this document

Imperial College Healthcare NHS Trust or participating sites will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Imperial College London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Imperial College Healthcare NHS Trust or participating sites will pass these details to Imperial College London along with the information collected from you and your medical records. The only people in Imperial College London who will have access to information that identifies you will be people who need to contact you to for study purposes or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Imperial College Healthcare NHS Trust will keep identifiable information about you from this study for 10 years after the study has finished.

HOW DO I FIND OUT ABOUT STUDY RESULTS?

Results of this study will be published on www.clinicaltrials.gov.org where the study is being registered. This is an open access website and you will be able to find this study by entering study name. Results will also be published in peer reviewed scientific journals, internal reports and presented on scientific conferences. You will not be identifiable in any report or publication.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

The sponsor of this study is Imperial College London.
The doctor conducting the research is not being paid for including and looking after you during participation in the study.

WHO HAS REVIEWED THE STUDY?

This study was given a favourable ethical opinion for conduct in the NHS by West London & GTAC Research Ethics Committee.

CONTACT FOR FURTHER INFORMATION

To discuss the study further please contact a member of the local research team on the following numbers:

Study Telephone: 0203 313 6713 (9am-5pm)
Study Mobile: 07776 224520 (24/7)

The email used for all study related matters is:

Imperial.covidcardio@nhs.net

[contact details of local research team]

PLEASE NOTE
If you are taking part in this study and are recovering so as to be discharged soon, please immediately contact our research team and let them know.

Thank you very much for taking part in this study!