PRESTIGE-AF

PREVENTION OF STROKE IN INTRACEREBRAL HAEMORRHAGE SURVIVORS WITH ATRIAL FIBRILLATION

Longitudinal MRI Substudy

Participant Information Sheet

WE INVITE YOU TO TAKE PART IN A SUBSTUDY OF PRESTIGE-AF

- 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 time to read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to decide whether to take part in this substudy. If you choose not to take part, this will not affect your participation in the PRESTIGE-AF Study and it will not result in any disadvantages for you.
- Ask us if there is anything that is not clear or if you would like more information.

BACKGROUND

The PRESTIGE-AF Study aims to answer the question of whether patients with intracerebral haemorrhage (ICH) and atrial fibrillation (AF) should take an anticoagulant medication or if it is better for them to avoid it. This will be primarily determined on the basis of clinical observation, i.e. the number of patients who have an ischaemic stroke (caused by a blood clot) or an ICH (caused by a bleed in the brain). We know, however, that changes in the brain may also occur unnoticed by the individual but can be depicted using a brain scan called

Magnetic Resonance Imaging (MRI). This substudy aims to measure changes in the brain which have occurred without causing noticeable symptoms. We would like to see if the changes are different in participants who are taking an anticoagulant compared with those who are not. This could be used as a further way to measure the benefit and risk of anticoagulant treatment.

WHAT IS INVOLVED?

If you have decided that you wish to take part in PRESTIGE-AF, you will also be asked to take some time to decide whether you are willing to take part in this substudy. If you agree to take part, you will have to complete and sign the informed consent form and will be given a copy to keep.

For this substudy we ask you to have one MRI brain scan which will be performed one year after you have been enrolled in PRESTIGE-AF. You have already had an MRI brain scan, since your ICH, it was performed to confirm the diagnosis and rule out other causes for your symptoms. The MRI scan for this substudy will take around 30 minutes.

An MRI scan poses no health risk because it does not use radiation (like an X-Ray), instead it uses a strong magnetic field and radio waves to produce images.

The MRI scans will be labelled with your PRESTIGE-AF participant ID number (i.e. all of your identifiable information will be removed) and will be sent electronically to the neuroimaging core lab for PRESTIGE-AF at the Department of Neurology, Medical University of Graz. There the scans will be interpreted and will be compared to the MRI which you had before you enrolled into the PRESTIGE-AF study.

Thereafter the images and date will be stored in an image data bank at the Medical University of Graz for 10 years. This is so that we can

reanalyse your scans if specific questions arise in the future or new techniques become available to capture changes in the brain.

POTENTIAL BENEFITS OF THE SUBSTUDY

In general, there will be no benefits for you personally from your participation in this substudy. However, if we can identify new brain imaging information, related to the response to oral anticoagulants, these results will be useful in the future to balance the benefits and risks when treating individuals like you with anticoagulants.

We will also notify the recruiting centre if brain abnormalities posing a new risk to your health, have occurred since your pre-study MRI. The recruiting centre will provide this information to you or to your doctor.

POTENTIAL RISK OF THE SUBSTUDY

There are no serious risks to participating in this substudy. The MRI examination does not depend on radiation.

Being inside the MRI scanner may cause some discomfort as you will need to lie still and the machine makes some loud noises during the scan. This will not be different from the MRI scan that you received before the study. During the scan you are lying in a tube which people who suffer from claustrophobia can find unpleasant. You should consider this when deciding whether to participate in this substudy.

Prior to having the scan, we will need to check that you are suitable to have an MRI. We will ask you some questions to check for any metallic implants since the pre-study MRI and if you are female you may be required to have a pregnancy test. Only patients in whom MRI is considered a safe procedure will be offered participation in the Longitudinal MRI substudy. While many cardiac pacemakers do not allow an MRI, patients with MRI safe pacemakers can be enrolled in the trial.

STUDY SPONSOR

The longitudinal MRI study is a substudy of the PRESTIGE-AF clinical trial. It is also sponsored by Imperial College London, which means that they are the responsible partners for the conduct of the study and all complaints, procedures, legal rights and insurance procedures are the same for the substudy as for the main PRESTIGE-AF Study.

As with the main study, this substudy is funded by the European Union's Horizon 2020 research and innovation programme under grant agreement No. 754517.

CONFIDENTIALITY & DATA PROTECTION

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 for 10 years after the study has finished.

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 contact hello@prestige-af.org.

Your Local NHS Trust will collect information from you and your medical records for this research study in accordance with our instructions.

Your Local NHS Trust will keep your name, NHS number and contact details confidential and will not pass this information to Imperial College London. Your Local NHS Trust will use this information as needed, 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. Certain individuals from Imperial College London and its delegates, as well as regulatory organisations may look at your medical and research records to check the accuracy of the research study. Imperial College London will only receive information without any identifying information. 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.

Your Local NHS Trust will keep identifiable information about you from this study for 10 years after the study has finished.

DATA SHARING

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with 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. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

This Study is sponsored and is run by Imperial College London. However, there are 11 other European partners in the Prestige AF

Consortium with whom we will be sharing the pseudonymised results of this study. These organisations are other Universities and Hospitals with specialist knowledge in different areas who will assist in the running of the study and the analysis and publishing of the data. The Partner Organisations are:

- University Hospital Würzburg, Germany
- Julius-Maximilans Universitaet Würzburg, Germany
- Medizinische Universitaet Graz, Austria
- The University of Birmingham, UK
- Kings College London, UK
- Fundacio Hospital Universitari Vall d'Hebron- Institut de Recerca, Spain
- Universite de Bordeaux, France
- Azienda Ospedaliera di Perugia, Italy
- Region Nordjylland (North Denmark Region) , Denmark
- Stroke Alliance for Europe, Belgium
- Heidelberg University Hospital, Germany

The aim of this research is to improve patient care and to help us do that we ask for you to consent to your data being used in future research studies. These studies would need to go through the same rigorous ethical screening procedure that we did, to get access to your data. All shared data will be anonymised, and no identifiable information will be given to anyone outside of the direct care team who look after you.

FURTHER INFORMATION

It is important that you have enough information to decide whether to take part. If you have any questions, please contact hello@prestige-af.org

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION.