PRESTIGE-AF

PREVENTION OF STROKE IN INTRACEREBRAL HAEMORRHAGE SURVIVORS WITH ATRIAL FIBRILLATION

Longitudinal MRI Substudy

Participant Information Sheet and Consent Form

For participants who regain capacity

Chief Investigator: Prof Roland Veltkamp

You were enrolled into a substudy of the PRESTIGE-AF Study by a relative, partner or close friend during a time when you were not well and were unable to make the decision for yourself. This substudy is still ongoing and now that you are able to make the decision for yourself, we would like to give you all of the information so you can decide if you want to keep taking part.

ABOUT THIS SUBSTUDY

- Before you decide whether to continue 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 continue to take part in this substudy. If you choose not to, 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 that 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 the main PRESTIGE-AF study. The research team will tell you If you have already had the research MRI scan, if you have, we are just asking if you are willing to let us keep and use your data.

If you haven't had the research MRI scan yet there is more information here to help you decide if you want to have it. 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 data 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

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 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 be the same as the MRI scan that you received before the study. During the scan, you are lying in a tube that people who suffer from claustrophobia can find unpleasant. You should consider this when deciding whether to participate in this substudy.

Before 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 for 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.

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 you should immediately inform the Investigator *(prestige-af@imperial.ac.uk).* The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

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 you personal data for:

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

We will need to use information from you, your medical records, your GP or other healthcare providers for this research project.

This information will include:

- Your name
- Your contact details
- Your NHS Number
- Health information

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.

Some of your information will be sent to countries in the European Union. They must follow our rules about keeping your information safe.

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.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). 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 European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other College employees, 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.

- This clinical trial is part of a large European Union funded project. We are working with the following research collaborators across Europe who are all specialists in different fields. In order to answer the questions of our research we are all working together and therefore your data will be shared with:

    - University Hospital Würzburg, Germany
    - Julius-Maximilans Universitaet Würzburg, Germany

- Medizinische Universitaet Graz, Austria
- 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
- University of Liverpool, UK

If you would like to find out more about the PRESTIGE-AF Project and what each partner does there is more information on our website www.prestige-af.org

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.

- If you agree to continue 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 hello@prestige-af.org

- www.prestige-af.org/privacy-cookie-policy/

COMPLAINTS

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
- 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 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.

FUNDER

A group of international researchers formed the PRESTIGE AF consortium, which applied for research funding. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 754517.

ETHICAL REVIEW

This research was designed and reviewed by a consortium of experts within the field. There are several monitoring boards in place that will continue to review the trial throughout, to ensure the safety of participants.

This research has been reviewed and approved by the London Surrey Borders Research Ethics Committee and the Medicines and Healthcare Products Regulatory Agency. The Health Research

Authority has approved this research to be conducted within the UK National Health Service.

FURTHER INFORMATION

It is important that you have enough information to decide whether to take part. If you have any questions, please contact the study team: *prestige-af@imperial.ac.uk*

Thank you for taking the time to read this information.

CONSENT FORM

Principal Investigator:

Participant ID:

	Please initial box
I confirm that I have read this information sheet and I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐
I understand that relevant sections of my medical notes and data collected during the study, may be looked at by responsible individuals from the NHS Trust or from regulatory authorities where it is relevant to my taking part in this research.	☐
I give permission for these individuals to access my records that are relevant to this research.	☐
I give / do not give (delete as applicable) consent for information collected about me to be used to support other research in the future, including those outside of the EEA.	☐
I understand that the information held and maintained by (*insert NHS Trust*) and other UK NHS bodies may be used to help contact me or provide information about my health status.	☐

I consent to continue to take part in the above study ☐

Name of Participant	Date	Signature
Name of Investigator taking consent	Date	Signature
Name of Witness (If oral consent given)	Date	Signature

When completed: 1 for Participant, 1 for investigator site file, 1 to be kept in medical notes