BRIEF PARTICIPANT INFORMATION AND CONSENT FORM

Study Code: D5130L00006 Subject Initials:

Centre No: Randomisation Code:

Study Title: **A 30 day international, randomized, parallel-group, double-blind, placebo controlled phase IV study to evaluate efficacy and safety of pre-hospital vs. in-hospital initiation of ticagrelor therapy in STEMI patients planned for PCI**

Short Title: A randomised study looking at ticagrelor therapy in STEMI patients

You are being asked to take part in this research study because you are suffering from a heart attack.

When you arrive at the hospital you will have a procedure to unblock the artery that is causing the heart attack. Before this procedure it is important that patients are given a drug to prevent blood clots from forming. This is usual clinical practice.

The drug in this study is called ticagrelor. It is a newly approved drug for the prevention of blood clots in patients with heart disease. We want to find out whether it is better to give ticagelor to patients while they are in the ambulance or after they arrive at the hospital.

In this study all patients will receive treatment with active ticagrelor. Half the patients will be given active ticagrelor in the ambulance and the other half will get the active ticagrelor at the hospital. Whether you get the active treatment in the ambulance or at the hospital will be decided by chance and neither you nor study site personnel will know when you were given the active treatment.

What Will Happen To Me If I Take Part?

The study is in two parts:
Part 1: Treatment with ticagrelor while in the ambulance or on arrival at hospital.
Part 2: All patients will continue treatment with active ticagrelor for about one month.

In Part 1 of the study all patients will take study medication as two tablets by mouth in the ambulance **and** on arrival at hospital. Half the patients will take active ticagrelor in the ambulance and the other half will be given an inactive drug called a placebo. The patients who get placebo in the ambulance will take active ticagrelor at the hospital. Those who receive active ticagrelor in the ambulance will receive placebo in the hospital.

What Are The Side Effects Of Study Medication?

Some patients treated with ticagrelor have had side effects such as nose bleeds, bleeding gums, bruises, shortness of breath or a slower heart rate. There are other possible side effects that happen less often.

There is always some risk when taking a new medication but every precaution will be taken to ensure your safety.

What Will Happen If I Don't Want To Carry On With The Study?

You can refuse consent now or if you go into the study you are free to withdraw your consent at any time without having to give a reason. This will not affect the standard of care you receive.

If you consent and later change your mind any information collected in the study up to that point may still be used. The study data that would be collected includes your name, address, date of birth, your sex, your ethnic origin and personal data on your physical and mental health or condition. More information on how your data will be used can be found in the full informed consent form.

Where can I get further information on the study?

This is a short version of the full consent form for use in the ambulance. If you decide to sign this form, you will be given a copy for your records.

As soon as the clinical situation allows you will be asked to sign the full consent form which has more information about the study. There will also be time to discuss the study with the Study Doctor at the hospital and to ask questions. If you decide to sign the full consent form, you will be given a copy to take home.

Thank you for taking time to read this information sheet.

To be signed and dated by the subject:

_____	_____	_____
Name of Patient (BLOCK CAPITALS)	Date	Signature
_____	_____	_____
Ambulance Crew Member (BLOCK CAPITALS)	Date	Signature

Time consent taken: __:__ (hh:mm) – to be completed by Ambulance Crew Member