Perth Blood INSTITUTE
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HAEMATOLOGY WEST

PARTICIPANT INFORMATION SHEET

Title of Study: Patient Satisfaction after Conversion from Warfarin to a Newer Oral Anticoagulant (NOAC) -------- The SWAN Study

Principal Investigator: Professor Ross Baker, Clinical Haematologist, Haematology West

Associate Investigators:

Dr Thomas Hendriks, Intern, Fiona Stanley Hospital, Haematology West
Mr Scott McGregor, Pharmacist, Haematology West
Mrs Julie Robinson, Clinical Trials Coordinator, Perth Blood Institute

INTRODUCTION

You are invited to take part in a research study that will assess your satisfaction with your current blood thinning treatment. The study will involve a simple survey/questionnaire that will give us a better understanding of the newer oral anticoagulants and how in particular they have impacted your life compared to your previous experience with warfarin. Your participation in this study would be greatly appreciated as you are one of the patients at Haematology West that was previously taking warfarin but have now converted to one of the newer oral anticoagulants (NOACs) – apixaban or rivaroxaban.

Please take the time to read the following information carefully and discuss it with your family, friends and/or general practitioner (GP). Should you have any questions or would like more information you can contact the research team at Haematology West on (08) 9200 2236 or at info@haemwest.com

NATURE AND PURPOSE OF THIS STUDY

The prescribing of newer oral anticoagulants (NOACs) such as rivaroxaban and apixaban for the prevention of blood clots is becoming more common as an alternative to warfarin.

The NOACs have different drug profiles and mechanisms of actions than warfarin, and in addition they do not require regular blood monitoring. Both rivaroxaban and apixaban are being used more frequently however there is limited information relating to patient satisfaction after making this change.

The aim of this study is to describe how you responded to your anticoagulant treatment and assess your satisfaction after converting from warfarin to a NOAC (rivaroxaban or apixaban).

Your satisfaction will be assessed through the use of a survey that will take approximately 5-10 minutes to complete. The survey is attached below and includes a questionnaire titled – the Anti-Clot Treatment Scale, and in addition some further questions regarding your experiences with NOAC therapy compared to your previous warfarin therapy.

The response to your anticoagulant treatment will be described through analysis of your past medical history and anticoagulation medication details obtained from your medical records at

Haematology West. These will be analysed by Dr Thomas Hendriks (associate investigator) who will also be conducting the survey.

WHAT PARTICIPATION IN THE STUDY INVOLVES

Should you **decide to participate** in this study then we ask that you kindly complete the attached survey and return it to Haematology West within two weeks.

By completing the questionnaire and returning it to Haematology West in the pre-addressed envelope, you are giving your consent for your questionnaire to be used in this study along with information from your medical history relating to your anticoagulant treatment recorded in your medical record at Haematology West.

If you **do not wish to be involved** then please return the Decline of Consent form (also attached) to Haematology West in the pre-addressed envelope.

Alternatively you can **email** us at info@haemwest.com or call us on **(08) 9200 2236,** should you wish to not participate.

If we haven't received a response from you by 20th June 2016, Dr Thomas Hendriks, associate investigator, will give you a courtesy call to confirm if you would still like to be included in the study. During that call, you will be given the option to complete the questionnaire with Dr Hendriks or to refuse to participate in the study.

EXPECTED STUDY DURATION AND NUMBER OF PARTICIPANTS

The expected duration of this study is three months. Approximately 100 participants attending Haematology West under the care of Professor Ross Baker will be recruited during this study. Analysis of the results will follow the close of the study.

Participants will be selected from patients that are under the care of Prof. Ross Baker, that have been switched from warfarin to a newer oral anticoagulant within the last three years.

STUDY PROCEDURES

This study only involves a 5-10 minutes written or telephone survey that will assess your satisfaction with your current anticoagulation treatment.

RISKS AND DISCOMFORTS

There will be no risks or discomforts in participating in this study.

POTENTIAL BENEFITS

This study will provide greater understanding of satisfaction and response to anticoagulant medication in patients who are treated with rivaroxaban or apixaban. Your participation in this

study may have no direct benefit for you, but may help with better management of those who will require anticoagulant treatment in the future.

PRIVACY AND CONFIDENTIALITY

The information gathered about you by the investigators or obtained during this study will be held by the investigators in strict confidence and all the people who handle your information will comply with the Privacy Act 1988. If the results of the trial are published in a medical journal, as is intended, no reader will be able to identify individual patients.

Information on the database will be retained for a minimum of 15 years in accordance with regulatory requirements. Participant files and other essential documents (study protocol, correspondence, and other documents pertaining *to the conduct of the study) must be kept for the* maximum period permitted by the research institute in accordance with these requirements.

Participant information will be deleted/disposed after this period.

COSTS TO PARTICIPATION

There will be no costs incurred as a result of your participation in this study and you will not be paid for your participation.

MEDICAL CARE/COMPENSATION

Your rights at Australian law do not change upon consenting to participate in this study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Participation in this study is entirely voluntary. You do not have to participate if you do not want to and your decision to participate or not will in no way affect your current or future care by your treating doctor. You are also free to withdraw from the study at any time without reason or justification.

CONTACT INFORMATION

If you have questions about this study, please contact **Professor Ross Baker on (08) 9200 2236** or **Julie Robinson, Research Nurse on (08) 9200 2236.**

This study has been approved by the Hollywood Private Hospital Ethics Committee. If you have any concerns about the conduct of this study or your rights as a research participant, please contact **Dr Terry Bayliss, Chairman of the HPH Ethics Committee on (08) 9346 6345** and quote the **ethics approval number HPH462.**