|  |  |
| --- | --- |
|  | **PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM** |
| Study Title | Prevention of Atrial Fibrillation After Coronary Artery Bypass Grafting (CABG) Surgery Using Tocotrienol, An Isomer of Vitamin E Derived From Palm Oil: A Randomized Controlled Trial |
| Name of investigator and institution | Dr Ahmad Farouk Musa, Monash University Malaysia |
| Name of sponsor | Hovid Berhad |
| Informed Consent Form Version | Version 2.0, dated 15 June 2017 |
| 1. **Introduction**

You are invited to take part voluntarily in a research study, looking into heart arrhythmia known as atrial fibrillation and the quality of life. The study will focus on the utilization of tocotrienol, an isomer of vitamin E, which is derived from palm oil, in preventing the occurrence of atrial fibrillation after surgery. Current studies have shown that tocotrienol possesses potent antioxidant activity. And considering the fact that atrial fibrillation is correlated with oxidative stress, there is a high probability that tocotrienol could prevent atrial fibrillation from occurring post-CABG. Thus this will subsequently reduce the complications associated with postoperative AF and also the economic burden of intensive care stay and prolonged hospital stay. With such understanding, we postulate that tocotrienol will exhibit beneficial effects for the prevention of atrial fibrillation after surgery that is known to correlate with higher morbidity and mortality. Overall, we also hypothesised that tocotrienol will increase the health related quality of life (HRQoL) of patients. But before agreeing to participate in this research study, it is important that you read and understand this form. It describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. If you participate, you will receive a copy of this form to keep for your records.Your participation in this study is expected to last up to two years. Up to two-hundred twenty six patients will be participating in this study.1. **Purpose of the Study**

The purpose of this study is to determine whether tocotrienol will prevent the occurrence of atrial fibrillation and subsequently reduces morbidity, length of stay in the hospital and improves the quality of life. This study will assess the quality of life utilizing Short-Form 36 Questionnaire (SF-36).1. **Qualification to Participate**

The surgeon in charge of this study or a member of the study staff has discussed with you the requirements for participation in this study. It is important that you are completely truthful with the doctor and staff about your health history. You should not participate in this study if you do not meet all the qualifications. Some of the requirements to be in this study are:1. Males or females

 2. More than 18 years of age 3. Elective, on-pump or off-pump surgery of coronary artery revascularization, single or double  procedure.You cannot participate in this study if:1. Less than 18 years of age
2. Refusal to have surgery
3. Urgent or emergency surgery
4. Inability to give informed consent
5. Documented history of adverse allergy to palm oil
6. **Study Procedures**

Once you have consented for coronary artery bypass surgery, you will be randomized into either receiving tocotrienol as a supplement or only placebo of palm superolein oil. The coronary artery bypass grafting surgery will be conducted as planned with all the necessary precautions including prophylactic antibiotics and proper closure of the chest and leg wound. You will be taking two capsules of 200mg tocotrienol each capsule a day from the first day of admission to a minimum of five days after surgery or alternatively palm superolein oil if you’re in the control group. After surgery, your heart rhythm will be monitored in CICU and HDU. You will be monitored continuously using an EPI life phone that will record your heart rhythm. Should you develop atrial fibrillation, the standard treatment will be instituted. The monitoring will be continued for the first four or five days on the wards until you are discharged.At six weeks, a postoperative clinic assessment will be arranged to further evaluation. A 12-lead ECG will be done during clinic visit.Your quality of life will be assessed using Short-Form 36 Questionnaire (SF-36) to assess your physical, social and emotional function. You will first receive your questionnaire one or two days before surgery and another assessment will be made before discharged and during the six-week follow-up at the clinic.1. **Risks**

Participation in this study involves no risk, side effects or discomfort that is additional to that of cardiac surgery itself. There will be continual review and monitoring of the efficiency and safety of the research project, and this will enable early detection of any problems you may experience.1. **Reporting Health Experiences**

If you have any injury, bad effects, or any other unusual health experience during this study, make sure that you immediately tell the nurse or the doctor in charge. You can call at any time, day or night, to report such health experiences.1. **Other Treatments**

You do not have to take part in this study to be treated for your illness or condition. Other treatments and therapies for your condition are available, including your current therapy. The study doctor can discuss these treatments and therapies with you.1. **Participation in the Study**

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop participation in the study at any time, without a penalty or loss of benefits to which you are otherwise entitled.The study doctor without your consent may also stop your participation. If you stop being part of this study, the study doctor or one of the staff members will talk to you about any medical issues regarding the stopping of your participation.1. **Treatment and Compensation for Injury**

If you follow the directions of the study doctor and staff and you are physically injured due to any substance or procedure properly given under the plan for this study, the treatment of that injury, which is not covered by your medical insurance, by a government program, or by any other third party, will be provided to you at no cost.If you have an illness or injury during this research study that is not directly related to your participation in this study, you and/or your insurance provider will be responsible for the cost of the medical care of that illness or injury.1. **Possible Benefits**

Study procedures will be provided at no cost to you. You may receive information about your health from any physical examination and laboratory tests to be done in this study.You will be paid RM50 as an honorarium to reimburse you for participation in this study. Information obtained from this study will benefit patients in the future.1. **Cultural acceptability**

The gelatin capsule used in the preparation of the study drug is made from bovine source.1. **Investigator Payment**

The doctors and/or his institution are not paid for their work in this study.1. **Questions**

If you have any question about this study or your rights, please contact Dr Ahmad Farouk Musa at 6012-232-1939, Dr Jeswant Dillon at 6012-293-7878, Dr Ezani Mohamed Taib, at 6012-382-7464 or Dr Alwi Yunos at 6012-202-6064.1. **Confidentiality**

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available unless disclosure is required by law.The principle researcher and/or its representatives may review your original medical records, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying clinical trial procedures and/or data. Your medical information may be held and processed on a computer.By signing this consent form, you authorize the record review, information storage and data transfer described above.1. **Signatures**

To be entered into the study, you or a legal representative must sign and date the signature page (see Attachment 1)**Patient Information and Consent Form****Attachment 1**To become a part this study, you or your legal representative must sign this page.By signing this page, I am confirming the following:* I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
* All of my questions have been answered to my satisfaction.
* I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
* I may freely choose to stop being a part of this study at any time.
* I have received a copy of this Patient Information and Consent Form to keep for myself.

 **Patient Name** **RN****Signature of patient** or Legal Representative **Date**  **Name of Individual** Conducting Informed Consent **Signature of individual** Conducting Consent **Date**   **Name & Signature of Witness** **Date**  |