

Instructions for investigators: Based on the type of study involved, the patient information sheet could vary. However it must be emphasized that the patient information sheet should be in simple language and should avoid medical/technical words as far as possible. Investigators are advised to use the same headings. The purpose of the study should highlight why the study is being carried out and how it will benefit the scientific community. Procedure should be of sufficient detail that a potential participant could understand as to what exactly they would be going through if they were to participate in the study. Patient information sheet is to be duly signed by the investigator.

Patient Information Sheet (template)

Title of the project: Evaluation of sorafenib in the treatment of pulmonary arterial hypertension - A randomized placebo controlled clinical trial.

Name of the principal investigator: Dr. Andrew Moses, Professor, Dept of Cardiology.

Name of the co-investigator: Dr. Raghavan K, Professor, Dept of General Medicine.

Purpose of this project/study:

Pulmonary Arterial hypertension (PAH) is a medical condition that causes increased suffering to patients including affecting the quality of life and placing them at high risk of worsening course of the illness. Although there are a number of medicines that are currently available in the market, none of these medication have been shown to substantially alter the course of the disease in the long term. Besides this, most of the current drugs also have several side effects that can also affect the quality of life. Sorafenib is a medicine that is existing in the market for the treatment of advanced kidney and liver cancer. Certain preliminary studies have shown a beneficial response of this molecule in the treatment of pulmonary arterial hypertension. However we are still not absolutely sure of how effective this molecule is in the treatment of PAH. The study aims to determine if sorafenib could improve the symptoms of the disease and also the safety of the molecule among patients with PAH

Procedure/methods of the study

You will be assessed of your eligibility to participate in the study by a number of blood tests performed once you give consent to participate in the study. These tests will be done free of cost and it will not incur any expenditure on you. You will be assigned to receive either sorafenib 200 mg or placebo twice daily for a period of 3 months. Placebo is a medication that is inactive and does not have therapeutic action. The assignment of the medication will be decided by chance, and you have equal chance of being assigned to each group. Your background medication will not be altered and would be continued. You will be expected to make three visits to the hospital- Visit1(0week), visit 2 (6th week)and Visit 3(12th week). At each visit 5 ml of blood will be collected for measurement of certain biomarkers. to see how the disease is progressing. We will also assess your ability to walk for a period of six minutes by measuring the distance you covered during a period of six minutes in a short corridor based on the number of trips you covered.

Expected benefits: You may receive a benefit of improvement of symptoms by participating in the study. However this may not happen always and depends on several factors which is difficult to predict.

Any risks expected from the study: Sorafenib is known to cause reduction in the hair, rash, fatigue, weight loss and diarrhea in certain patients. All adverse reactions will be monitored and treatment will be provided at the hospital free of cost if the PI feels the reaction is due to the study drug.

Compensation: In case of any serious adverse reaction occurs to you, you will be provided compensation if it is proven that the medication has caused the illness. If the reaction has occurred due to reasons apart from study medication such as disease worsening, or failure to take study medication you will not be provided compensation.

The decision regarding payment of compensation will be taken by a group of experienced doctors and scientists who are not connected with the study. Your participation in the study will be kept confidential. You are free to withdraw from the study at any

time during the study period. Your withdrawal will not affect your treatment in the hospital and you will continue to receive all benefits which you routinely receive from the hospital.

Address & contact of the principal investigator

Dr. Andrew Moses, Professor, Dept of Cardiology, SRM Medical College Hospital. Phone- 543456789871

Informed consent Form (template)

Study Title: Evaluation of sorafenib in the treatment of pulmonary arterial hypertension - A randomized placebo controlled clinical trial.

Study number:

Subject initials:

Age:

Subject Name:

I confirm that I have read and understood the information sheet dated _____ for the above study. I have had the opportunity to ask questions and all the questions were answered to my satisfaction.. I understand that my participation in the study 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 the investigator and the ethics committee will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However I understand that my identity will not be revealed in any information released to third parties or published. I agree not to restrict the use of any data or results that arise from this study provided that such a use is only for scientific purpose.

I agree to take part in the above study

Signature (or thumb impression) of the subject _____ Date:

Signatory name: _____

Signature of the Legally Accepted Representative

_____ Date: _____

Signatory name: _____

Signature of the investigator _____ Date

Study investigator name: _____

Signature of the witness: _____

Date: _____

Name of the witness: _____