

Patient Educational Sheets

Dear future participants

Allow me to introduce myself, my name is **Budi Setiawan**, I am a student of the Doctoral Program in Medicine and Health at Diponegoro University. In order to get a Doctorate degree, one of the conditions set for me is to compile a dissertation or research. The research I am going to do is entitled: : **“The effectivity of atorvastatin for deep vein thrombosis prophylaxis in cancer patients.”**

Before giving your consent, you are asked to read this document which contains information about this research and what treatment was carried out

What is The Purpose of This Research?

The purpose of this study was to determine the effect of Atorvastatin administration compared to Rivaroxaban on reducing inflammatory responses, activation of coagulation cascade and the incidence of deep vein thrombosis in high-risk cancer patients who undergo chemotherapy through various markers of disease activity.

What is Deep Vein Thrombosis ?

Deep vein thrombosis is a condition in which blood clots form in deep veins in the veins of the legs or pelvis which can cause pain, pain and leg swelling. On physical examination, there is local pain, swelling, discoloration and dysfunction in the affected limb. Examination of the legs with TVD revealed localized swelling accompanied by pitting edema, reddish skin, tenderness, warm skin touch, enlarged superficial veins, and in severe obstruction the skin is bluish in color.

Blood clots in the blood vessels in the legs, if loose, can also enter the blood circulation into the heart. From the heart, the blood clots can be pumped into the lungs, but because the blood vessels of the lungs are smaller, blood clots can occlude the blood vessels leading which is called pulmonary embolism. If this happens, the patient will complain of shortness of breath, and if you don't get help it will cause death.

Cancer patients have a condition where the blood tends to coagulate more easily thus increase the risk of deep vein thrombosis. The incidence of deep vein thrombosis is high in cancer patients undergoing chemotherapy. Chemotherapy increases the risk of deep vein thrombosis sixfold and repeated deep vein thrombosis events twofold higher. Deep vein thrombosis is a major cause of increased death, morbidity, delayed treatment, and treatment costs. In addition, deep vein thrombosis in cancer causes the risk of recurrent deep vein thrombosis, bleeding complications, the need for long-term anticoagulant, and interferes with chemotherapy programs.

Deep vein thrombosis can be diagnosed based on symptoms and signs as well as examinations such as Doppler ultrasound which will be performed in this study.

What is The Research Protocols and Procedures?

If you meet the sample criteria, then you will be selected as a candidate for the research sample. Before the research began, the researcher explained to the research subjects about the research objectives, examination procedures and the benefits to be obtained.

Subjects who agreed to take part in the research were asked for proof their consent by putting a signature or thumbprint on the consent form after explanation. The history and clinical examination data were recorded on the basic data questionnaire sheet.

The subjects of the study were performed blood sampling to examine disease activity markers in the laboratory. If the research subject found signs and symptoms of deep vein thrombosis, a Doppler ultrasound examination would be performed on the affected leg to prove the presence of a blood clot in the leg vein. If during 3 months of observation there were no signs and symptoms of deep vein thrombosis, Doppler ultrasound was performed at the third month of the study to prove the presence or absence of deep vein thrombosis.

What is The Risk That Could Happen to Me if I Agree to Participate?

In this study, we will conduct interviews for you to fill out questionnaires and take 20-30 cc of venous blood samples taken at once or in stages according to the patient's condition. You will experience a little pain and dizziness, especially for those who are not familiar with blood tests, but sometimes there is a swelling or bruising effect on the site of the blood draw.

When taking research drugs, alteration of liver function may sometimes occur. But in general, the drug is well tolerated and serious side effects are rarely found. Other side effects associated with this therapy are myopathy, spontaneous pain or muscle tenderness and muscle weakness.

Sometimes bleeding is also found when taking medication. Bleeding can be found in the gums, skin, along with urinating or defecating. We will rigorously evaluate with physical and laboratory examinations for events that may occur.

What Are The Benefits May I Obtain If I Agree to Participate ?

The benefit of this research for you is that it can help the healing process of your cancer faster, because hopefully during chemotherapy you will not fall into a deep vein thrombosis condition which causes deterioration of your cancer condition. All drug costs and examinations during the study are the responsibility of the researcher.

Can I Withdraw From This Research?

Your participation in this research is voluntary. You have the right to refuse to participate in this research or to withdraw from the research at any time without any sanctions or forfeiting your rights to get cancer therapy according to the procedure.

How About The Confidentiality?

All data taken from you, including sample, will be marked with a specific number to ensure that your identity is kept confidential. Only researchers or research doctors have information that can link the code number to your name.

Who has examined this research?

The ethical committee / scientific committee approved this information sheet and consent to the release of patient data and study protocols. For more information you can contact the ethics committee team at:

Ethics Committee Team : Health Research and Ethics Committee, Faculty of Medicine

Diponegoro University and RSUP Dr. Kariadi Semarang

Address : Dekanat Office FK UNDIP Fl. 3, Dr. Sutomo St. No. 18, Semarang

Phone Number : 024 8318350

Who Can be Contacted to Get Further Information ?

Contact name for more information on all matters relating to this research:

Name : Dr. Budi Setiawan, SpPD, K-HOM, FINASIM

Title : Hematologist and Medical Oncologist

Address : Jl. Badak Raya No. 74 Semarang

Position : Main Researcher

Phone : 085865118118

For your attention and cooperation, we thank you.