Alliance A091105

A multicenter, phase III, double blind, randomized, placebo-controlled trial of sorafenib in desmoid tumors or aggressive fibromatosis

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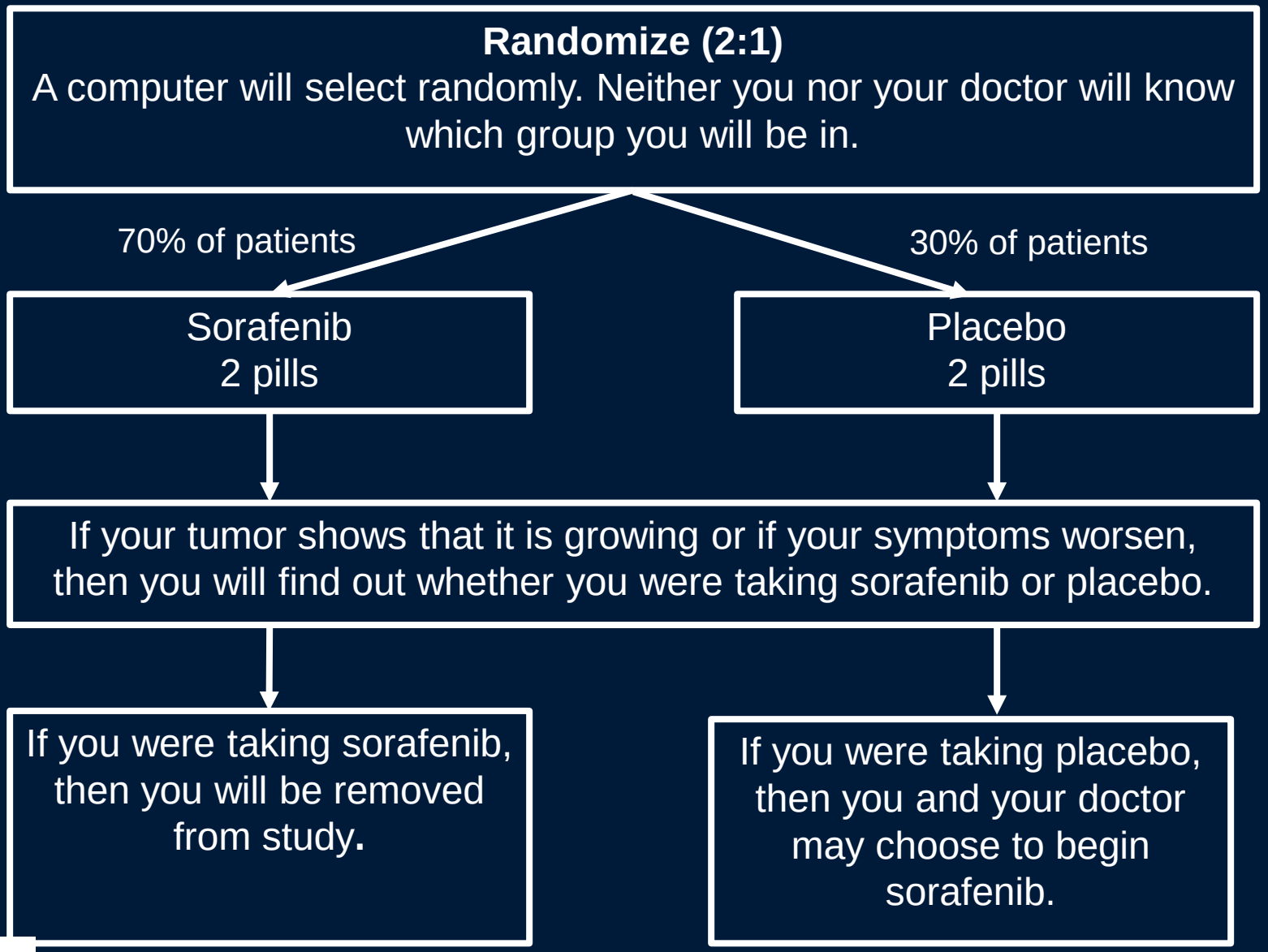
Study Chair

NCT #: NCT02066181



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Frequently Asked Questions

Q1: Why is clinical trial being done?

The purpose of this study is to compare the safety and effects of sorafenib vs. placebo on the growth of your desmoid tumor. At the present time, sorafenib is approved by the health authorities (U.S. Food and Drug Administration or FDA) to treat liver or kidney cancers. Research has shown that sorafenib may be beneficial in the treatment of desmoid tumors.

Q2: What is the cost of taking part in this study?

Sorafenib/Nexavar will be provided free of cost if you participate in this study. You and/or your health insurance plan/insurance company will need to pay for all of the other costs of treating your desmoid tumor(s) while in this study, including the cost of tests, procedures, or medicines to manage any side effects.

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Frequently Asked Questions

Q3: Will I get a placebo?

There is a 30% chance that you may get a placebo when you first start the study. The term “placebo” also means “sugar pill.” Neither you nor your doctor will know whether you are getting the placebo or sorafenib. The pills look identical. While you are on this study, you will get MRI or CT scans every 2 months. If your scan shows that your tumor is growing or your symptoms worsen, your doctor will discuss this with you and you have the option of getting sorafenib. Your doctor can explain this more.

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Frequently Asked Questions

Q4: How long can I be in the study?

You will be in this study as long as your doctor thinks it is safe and beneficial to you or until your disease progresses while taking sorafenib.

Q5: Can I participate if I no longer have desmoid tumor or if my tumor is not growing?

You cannot participate if you no longer have desmoid tumor. If your tumor is not causing any symptoms or is not growing then you are not eligible to participate. Ask you doctor about this as this is a complex decision making process.

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Frequently Asked Questions

Q6: Why are biopsies being done in this study?

Biopsy of your tumor is optional. You can choose not to get a biopsy and still participate in this study. Doctors and scientist do not understand what causes desmoids to occur and grow. The biopsy (and other samples collected on the study) may help them learn more. You will get local anesthesia and a small needle will be used to take a tiny amount of tissue from the tumor. You doctor can explain this in greater detail.

Q7: Why are questionnaires administered as part of this study?

You will be asked to participate in taking optional questionnaires as part of this study. You can choose not to answer these questionnaires and still participate in this study. These questionnaires ask how your symptoms are before you started the study and after you started the study. These questions help understand what are the symptoms and issues that desmoid tumor patients face. There are about 20 questions that you will be asked to answer.

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Frequently Asked Questions

Q8: Will I get a CT scan or MRI? How often are scans performed?

You will get a CT or MRI scan before you start the study and after you start the study. You will get scans every 2 months. Your doctor will decide whether you need a CT or MRI.

Q9: Where is this study being conducted and how can I learn more?

This study is being conducted at many hospitals throughout the country. A hospital close to you may offer this study. This list is constantly updated and can be found at: http://clinicaltrials.gov/show/NCT02066181

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