

Are there possible side effects?

You may experience side effects while in this study. Your doctor or nurse will explain them to you.

What are the costs of the study?

There are no extra costs for this study. You or your health insurance provider will need to pay for some or all of the costs of treating your cancer in this study. Check with your health insurance provider to find out what they will pay for. Taking part in this study may or may not cost your insurance provider more than the cost of getting regular cancer treatment. You or your insurance will not be charged for the cost of sorafenib.

Am I required to be in this study?

No. Taking part in this study is voluntary. You are free to choose to participate, not to participate, or to leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

How do I participate?

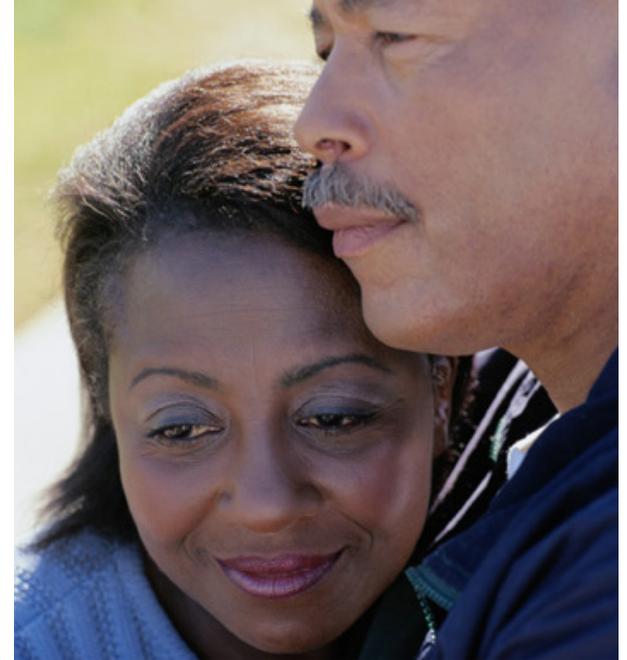
If you are interested in this study, please speak to your doctor and the members of your health care team to discuss the possible benefits and risks of participating.

Who is conducting this study?

This study is being conducted by the Alliance for Clinical Trials in Oncology. The Alliance is a research network funded by the National Cancer Institute (NCI).

Where can I get more information?

For more information, contact the National Cancer Institute Cancer Information Service toll-free at 1-800-422-6237 or visit their website at www.cancer.gov. You can also visit the Alliance website at www.AllianceforClinicalTrialsinOncology.org.



If you are a patient with desmoid tumors or aggressive fibromatosis (types of sarcoma), you may want to consider joining a clinical study.

Alliance A091105: A study that looks at whether or not a new drug benefits people who have desmoid tumors (DT) or aggressive fibromatosis (DF)



What is a clinical study?

Clinical studies (or “trials”) are a type of research involving patient volunteers. They are designed to test different ways to treat disease. It is not known what effects good or bad the proposed treatment will have until the study has been completed.

What type of study is this?

This study is a clinical trial looking at a new drug treatment. There are other therapies that are used in this disease such as surgery, radiation, or medications.

Who can participate in this study?

You can participate in this study if:

- You stopped taking other treatment for desmoid tumors (DT) or aggressive fibromatosis (DF) at least 4 weeks ago.
- Your tumor has grown, is causing more pain, or cannot be operated on.
- You have never taken sorafenib before.

Why is this study being done?

There is no standard treatment for desmoid tumors or aggressive fibromatosis. The purpose of this study is to compare how long people live without their cancer getting bigger after taking sorafenib or a look alike pill that has no active drug in it (placebo). Sorafenib is currently used in treating kidney, liver and thyroid cancer. If you are assigned to placebo and your symptoms or tumor gets worse then you can choose to be switched to sorafenib.

This study is also being done to measure side effects and pain levels, track how long it takes

before surgery can be done, learn how tumors respond, and how long people live. They will also collect tumor tissue to see if they can find tumor markers that can help predict who does well and who doesn't do well with this treatment.

What is involved in the study?

If you decide to participate in this study, you will read and sign a consent form that explains the study in detail. If you meet all the study requirements, you will be enrolled in the study.

What will I have to do during the study?

If you choose to participate in this study, you will have some tests done to make sure that you are eligible for this study:

- CT or MRI scans
- Blood tests
- Survey that asks about your quality of life

Once enrolled in the study, you will begin taking a pill daily and keeping a daily diary. Neither you nor your doctor will know if you are taking sorafenib or placebo. If your tumor(s) grows or your symptoms worsen, you will be able to change treatment and get sorafenib if you were in the placebo group.

You may choose to participate in optional quality of life and tumor tissue studies. You can still take part in the main study if you choose not to participate in the optional studies.

What is involved in a tumor biopsy?

Biopsy of your tumor before and during the study is optional. You can still take part in the main study if you choose not to participate in the optional studies. Doctors will do research on this tumor biopsy to understand how desmoid tumors grow and are affected by sorafenib.

What are the benefits of being in the study?

This study will help doctors learn more about the treatment of desmoid tumors and aggressive fibromatosis. The findings of this study may help future patients with these cancers.

