Alliance Public Study Result Summary
Study Number A091105

What this study is about

A cancer study that looked at using the drug sorafenib to treat desmoid tumors (aggressively growing fibromatosis).

The full title of this study is: A Phase III, Double Blind, Randomized, Placebo-Controlled Trial of Sorafenib in Desmoid Tumors or Aggressive Fibromatosis (DT/DF)

Why the study was done

This study was done to see if it is safe and effective to give sorafenib to slow the growth of desmoid tumors.

Study results

These results are for people with fast growing, symptomatic or recurrent desmoid tumors who participated in this trial.

The study found that:

- The chance of a patient having no tumor growth 2 years after starting the drug sorafenib was 81% (81 patients out of every 100 patients).
- The chance of having no tumor growth 2 years after starting the placebo was 36% (36 out of every 100 patients).

The most common side effects found in 20-80% (20 to 80 out of every 100) people included:

- Anemia which may require blood transfusion
- Pain
- Diarrhea, nausea
- Tiredness
- Bruising, bleeding
- Weight loss, loss of appetite
- Infection, especially when white blood cell count is low
- Hair loss, rash
- Redness, pain or peeling of palms and soles

What the results mean

This means that treatment with the drug sorafenib appeared to be effective in slowing the growth of desmoid tumors in patients with fast growing, symptomatic or recurrent tumors.

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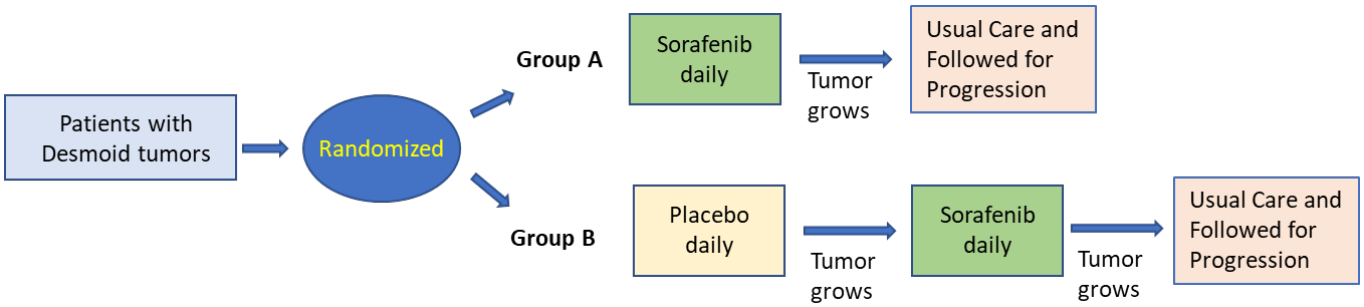
How the study worked

Here's a picture that explains how patients were placed into this study.



Randomization is the process by which patients are assigned by chance to separate groups.
Sorafenib is a pill taken by mouth every day. One dose of 400mg was used in this study.
Placebo is a pill taken by mouth every day that does not contain medicine and looks the same as the drug

Patients with aggressive desmoid tumors were randomly assigned to receive either sorafenib (Group A) or a placebo (Group B). Treatment assignment allowed for more patients to be assigned to sorafenib (versus placebo). Neither the patient nor their doctor knew if the patient was receiving the drug or placebo (also known as a double-blind study). Treatment continued until a patient's tumor grew. If the tumor grew too large, patients and their doctors were told which treatment they were receiving. For those patients who had received the placebo and whose tumor grew, these patients could then receive sorafenib. For those patients who had originally received sorafenib and whose tumor grew, these patients were monitored and cared for by their physician. All patients were followed until either death or 5 years had passed.

When did the study start and end? The study started in March, 2014. All patients were enrolled by January 2016.

How many patients joined? 87 patients agreed to be in this study.

Talk to your doctor if you want more information about this study.

Scientific publications about this study

Details about the study can be found in these articles:

- Gounder MM, Mahoney MR, Van Tine BA, Ravi V, Attia S, Deshpande HA, Gupta AA, Milhem MM, Conry RM, Movva S, Pishvaian MJ, Riedel RF, Sabagh T, Tap WD, Horvat N, Basch E, Schwartz LH, Maki RG, Agaram NP, Lefkowitz RA, Mazaheri Y, Yamashita R, Wright JJ, Dueck AC, Schwartz GK. Sorafenib for Advanced and Refractory Desmoid Tumors. N Engl J Med. 2018 Dec 20;379(25):2417-2428. doi: 10.1056/NEJMoa1805052. PMID: 30575484; PMCID: PMC6447029

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/NCT02066181

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This summary lists what is known about this research study as of November 2020. New Information may be available.

We thank the people who joined this study and made it possible.
We do research to try to learn the best ways to help patients.
The people who joined this study helped us to do that.

Thank you for your interest in learning more about cancer research advances.