



ALLIANCE TRIAL AT-A-GLANCE

Title

Randomized Phase II Study of Sorafenib With or Without Everolimus in Patients with Radioactive Iodine Refractory Hürthle Cell Thyroid Cancer

Study Chair

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Details

- Status: **Accepting New Patients**
- Study Type: Therapeutic, Treatment
- Protocol No: Alliance A091302
- [ClinicalTrial.gov Identifier: NCT02143726](https://clinicaltrials.gov/ct2/show/study/NCT02143726)

Purpose

The purpose of this study is to test whether of using everolimus along with sorafenib tosylate versus sorafenib tosylate alone in treating patients with advanced radioactive iodine refractory thyroid cancer will cause more shrinkage of thyroid cancer and prevent it from growing, and whether it could also cause more side effects than sorafenib tosylate alone.

Overview

This is a randomized study for patients with metastatic Hürthle cell thyroid cancer for whom radioactive iodine is found not to work. Participants will be randomized to either receive sorafenib alone or sorafenib in combination with the study drug, everolimus. If a patient receives sorafenib alone and the tumor starts to progress while on the drug, they can then “cross-over” and receive everolimus alone.

This study is based on a phase II study of sorafenib and everolimus in patients with metastatic thyroid cancer. In the study, nine patients had Hürthle cell thyroid cancer and seven of them had major responses to the combination. Preclinical data with Hürthle cell thyroid cancer suggest that the pathway by which everolimus inhibits is important for this type of tumor to grow.

Eligibility

The important eligibility criteria for the study includes:

- The diagnosis of Hurthle cell thyroid cancer
- The disease is not curable through surgery or radiation therapy
- No prior sorafenib use (although the prior use of other treatment such as pazopanib or lenvatinib is allowed)

Note: This is only a partial list of eligibility criteria. Please contact the study chair for complete screening information if you are interested in this clinical trial.

About the Alliance

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