Alliance Public Study Result Summary
Alliance A031203

What this study is about

This study compared different drug treatments in patients with newly found kidney cancer that had spread from where it started to nearby tissue or to other places in the body.

The full title of this study is: Randomized phase II study comparing cabozantinib (NSC #761968) with commercially supplied sunitinib in patients with previously untreated locally advanced or metastatic renal cell carcinoma

Why the study was done

The usual treatment for patients with newly found kidney cancer is to get a drug called sunitinib (common brand name sutent).

This study was done to see if a new drug called cabozantinib (common brand names cabometyx, cometriq) was as good or better than usual treatment with sunitinib in patients with newly found kidney cancer that had spread to nearby tissue or to other areas of the body. All patients in the study had kidney cancer that was intermediate or poor-risk clear cell type.

The study done was to see if the patients treated with cabozantinib would experience a longer time until their cancer grew as compared to the patients who were treated with sunitinib. The study also was done to determine how long patients lived and what side effects patients had.

Study results

These results are for patients with newly found kidney cancer that had spread to areas outside of the kidney.

During the study, patients getting cabozantinib had a longer time until their cancer grew larger as compared to patients getting sunitinib. Patients getting cabozantinib had 2.6 months longer until their cancer began growing. Cabozantinib was better at keeping the cancer from growing than usual treatment with sunitinib in patients with newly found kidney cancer that had spread to nearby tissue or to other areas of the body.

The most common serious side effects with cabozantinib included:

- High blood pressure: *about 3 out of 10 patients*
- Watery and frequent stools: *about 1 out of 10 patients*

The most common serious side effects with sunitinib included:

- Extreme tiredness: *about 1.5 out of 10 patients*
- High blood pressure: *about 2 out of 10 patients*
- Watery and frequent stools: *about 1 out of 10 patients*
- Low levels of platelets, which can cause inceased bleeding: *about 1 out of 10 patients*

About 6 out of 10 patients treated with cabozantinib and 1 out of 5 patients treated with sunitinib had the dose of their drug reduced because of bad side effects.

What the results mean

The results of this study mean that cabozantinib was better at getting kidney tumors to stop growing and keeping the kidney tumors from getting larger for a longer period of time.

Cabozantinib is a good treatment option for patients with newly found kidney cancer which has spread and is intermediate to poor-risk clear cell type.

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Longer follow up of the patients on this study is planned to determine if patients getting carbozantinib live longer than patients getting sunitinib.

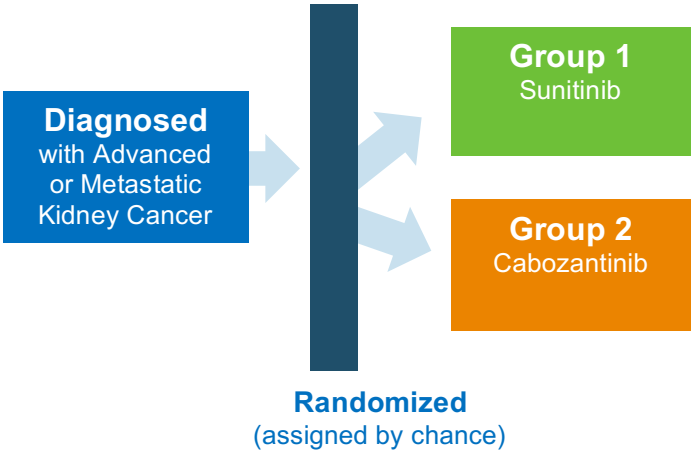
How the study worked

Patients were assigned by chance (randomized) to one of two groups. This made sure that each patient had the same chance of being in any study group.

- Group 1 got sunitnib. Sunitinib was a pill taken by mouth once a day for four weeks followed by a two-week break from treatment.
- Group 2 got cabozantinib (the new drug). Cabozantinib was a pill taken by mouth once a day for six weeks.

Patients remained on treatment until their kidney cancer grew larger or spread to other parts of their body.

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



When did the study start and end? The study started in July 2013. All patients were enrolled by April 2015.

How many patients joined? 157 patients agreed to be in this study.

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

Scientific publications about this study

This summary includes information in the following article:

- **Cabozantinib versus Sunitinib as Initial Targeted Therapy for Patients with Metastatic Renal Cell Carcinoma of Poor or Intermediate Risk: The Alliance A031203 CABOSUN Trial.** Choueiri TK, Halabi S, Sanford BL, Hahn O, Michaelson MD, Walsh MK, Feldman DR, Olencki T, Picus J, Small EJ, Dakhil S, George DJ, Morris MJ. J Clin Oncol. 2017 Feb 20;35(6):591-597. doi: 10.1200/JCO.2016.70.7398. Epub 2016 Nov 14.

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/NCT01835158

This study was sponsored by the Alliance for Clinical Trials in Oncology – a national clinical trial network group that runs large cancer clinical trials. The Alliance is supported by the National Cancer

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Institute (NCI) and brings researchers together to develop better treatments for cancers. More information about the Alliance is at http://www.allianceforclinicaltrialsinoncology.org.

This summary lists what is known about this research study as of November 2016.
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.