Alliance Public Study Result Summary
NCCTG N0871

What this study is about

A study that compared different drug treatments in patients with previously untreated cancer of unknown primary.

The full title of this study is: A phase II study of carboplatin (CBDCA), paclitaxel (TAXOL), and everolimus (RAD001) in previously untreated patients with measurable disease with cancer of unknown primary (CUP)

Why the study was done

When cancer goes to other parts of the body (metastatic), it came from a different tissue (the primary site). Some patients have metastatic cancer that is called cancer of unknown primary (CUP) because is hard to tell where the cancer came from. This means it is hard to know which treatments will work best in these patients. Patients are usually treated with carboplatin (common brand name paraplatin) or paclitaxel (common brand name taxol), but these drugs do not always stop the cancer from growing.

This study was done to look at a better way to treat patients with CUP – if adding a new drug called everolimus (common brand names afinitor, zortress, afinitor disperz) to carboplatin and paclitaxel stopped these cancers from growing. This study also looked at the biology of the tumors in more detail to help identify the tissue where the tumor came from (primary site). In addition, the study looked if that tumor information could be used to tell which patients may do better when everolimus is added to the usual treatment.

Study results

These results are for people with metastatic cancer of unknown primary.

All patients got everolimus plus carboplatin and paclitaxel.

The study found that

- Of all patients treated with everolimus plus carboplatin and paclitaxel
  - Tumors became smaller in 1 out of 3 patients (36%)
  - Tumors did not grow in 1 out of 3 patients (33%)
  - Tumors grew in 1 out of 3 patients (29%)
- The biology of the tumors was looked at by a test called Gene Expression Profiling (GEP). This test could identify patients whose tumors might be more likely to stop growing or become smaller when everolimus is added to carboplatin and paclitaxel.

Significant side effects were seen in 40 out of 46 patients (87%).
The most common side effects included:

- Decreased number of white blood cells which can negatively impact the ability to fight infections: in 2 out of 3 patients (67%)
- Decreased number of red blood cells which can make one feel tired or fatigued: in 1-2 out of 10 patients (15%)
- Other adverse effects of the study drugs included:
  - Hypersensitivity reactions (drug allergy): in 1-2 out of 10 patients (13%)
  - Increase in liver enzymes which can indicate liver disease: in about 1 out of 10 patients (7%)
  - Low sodium levels in your blood which can cause weakness, fatigue, headaches and other symptoms: in 1 out of 10 patients (9%)
  - Numbness and tingling in your hands and feet: in 1 out of 10 patients (9%)

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What the results mean

This means that adding everolimus to carboplatin and paclitaxel:

- Was a promising treatment with 2 in 3 patients having their tumors stop growing or getting smaller
- Patients experienced acceptable and manageable side effects
- A tumor test (derived from GEP) may further identify patients who are most likely to benefit from adding everolimus to carboplatin and paclitaxel

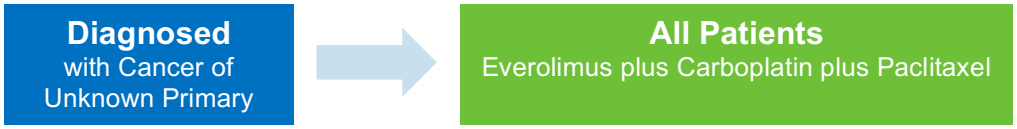
These results show the promise and need for more studies in CUP to identify more ways to treat these cancer patients based on newly developed ways to look at the biology of the tumor.

How the study worked

All patients with metastatic, previously untreated CUP got everolimus plus carboplatin and paclitaxel.

Prior to treatment, a part of the tumor was taken. The tumor tissue was tested using GEP to look at the biology of the tumor.

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



When did the study start and end? The study started in October 2009. All patients were enrolled by October 2012.

How many patients joined? 46 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:

- **Gene Expression Profiling Identifies Responsive Patients with Cancer of Unknown Primary Treated with Carboplatin, Paclitaxel, and Everolimus: NCCTG N0871 (Alliance).** Yoon HH1, Foster NR2, Meyers JP2, Steen PD3, Visscher DW4, Pillai R5, Prow DM6, Reynolds CM7, Marchello BT8, Mowat RB9, Mattar BI10, Erlichman C1, Goetz MP11. Ann Oncol. 2016 Feb;27(2):339-44. doi: 10.1093/annonc/mdv543. Epub 2015 Nov 16.

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/NCT00936702

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 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 2015.
New Information may be available.

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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.