What this study is about

This study compared the amount of nerve pain that cancer patients had in their hands and feet with or without a drug

The official title of this study is:
CALGB 170601: A phase III double blind trial of oral duloxetine for treatment of pain associated with chemotherapy-induced peripheral neuropathy (CIPN).

Why the study was done

About 2-4 cancer patients out of every 10 (20-40%) get severe nerve pain in their hands and feet if they take chemotherapy drugs that cause this side effect. These drugs are known as taxanes and platinums. This kind of pain is also called "peripheral neuropathy." Nerve pain makes it hard to do every day activities. Most drugs do not help this kind of pain.

Past studies show that an approved drug called duloxetine (or brand names like Cymbalta®) is safe and has low side effects for most people. Duloxetine was tested in this study for two reasons.

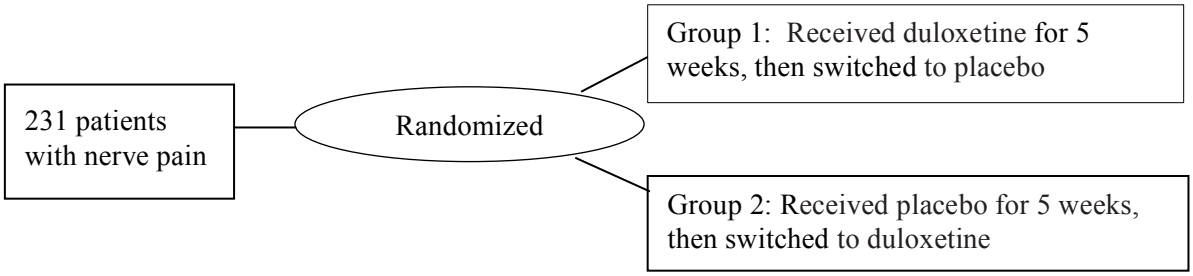
1. Past studies show that duloxetine works for diabetes patients who have nerve pain in their hands and feet. Researchers thought it might also work for cancer patients.
2. Duloxetine works by increasing the amount of two chemicals (called serotonin and norepinephrine) that can stop or lower pain.

The study was done to see if duloxetine decreases nerve pain levels that are caused by chemotherapy. They also studied its effect on normal pain levels.

Patients were put into two groups by chance (randomized) to reduce differences between the groups. This was done because no one knew if one treatment was better than another. In this study, the doctor and patient did not know if the pill was duloxetine or a look-alike pill (called a placebo).

Half the patients got a duloxetine pill and the other half got a placebo pill. After 5 weeks of treatment, patients switched to the other group for another 5 weeks. Total treatment lasted for 10 weeks. All participants received duloxetine in one of the 5-week treatments.

Here is a picture that explains how patients were placed into one of 2 groups.



When did the study start and end? The study started in April 2008. All patients were enrolled by March 2011 and study follow-up was finished in July 2012.

How many patients joined? 231 patients who were 25 years or older agreed to be in this study.

Study results

Important findings:

- Patients who took duloxetine had less pain than those who took placebo.
- About 6 of 10 patients (59%) who took duloxetine had less pain, compared to about 4 of 10 patients (38%) who took placebo.
- Three of 10 patients (30%) who took duloxetine had no change in pain level, and 1 of 10 patients (10%) had increased pain.
- Patients who took duloxetine were able to do their daily activities better.
- Patients who took duloxetine rated the quality of their lives higher than those who took placebo.

Other findings:

- After the first 5-week treatment, about 4 of 10 patients (41%) who got duloxetine had less numbness and tingling in their feet, compared to about 2 of 10 patients (23%) with placebo.
- Patients who took platinum chemotherapy drugs (like oxaliplatin) may have had better pain relief from duloxetine than patients who took taxane chemotherapy drugs (like paclitaxel or docetaxel).

What the results mean

This means that duloxetine helped lower pain levels for most cancer patients who had severe nerve pain in their hands and feet from chemotherapy. Duloxetine may work better with platinum drugs instead of taxane drugs.

These results are for cancer patients over 25 years old who have nerve pain due to chemotherapy.

Scientific publications about this study

Results are published in the following journal article:

Smith, E. L., Pang, H., Cirrincione, C., Fleishman, S., Paskett, E. D., Ahles, T., Bressler, L. R., Fadul, C., Knox, C., Gilman, P. B., Shapiro, C. L. (2013). Effect of duloxetine on pain, function, and quality of life among patients with chemotherapy-induced painful peripheral neuropathy: A randomized clinical trial. *JAMA*, *309*(13), 1359 – 1367.

You can also talk with your doctor for more information.

This sheet reviews what is known about this research study as of January 2013. New Information may be available.

This study was sponsored by Alliance for Clinical Trials in Oncology (Alliance) – a national cooperative group that runs large-scale cancer clinical trials. The Alliance is supported by the National Cancer Institute (NCI) and brings researchers together to develop better treatments for cancer. More information about the Alliance is at allianceforclinicaltrialsinoncology.org/main/public/index.xhtml.

Research studies (or clinical trials) are done to learn what works better for people in order to find, treat, or prevent cancers. Thank you for your interest in learning more about cancer research advances.