What this study is about

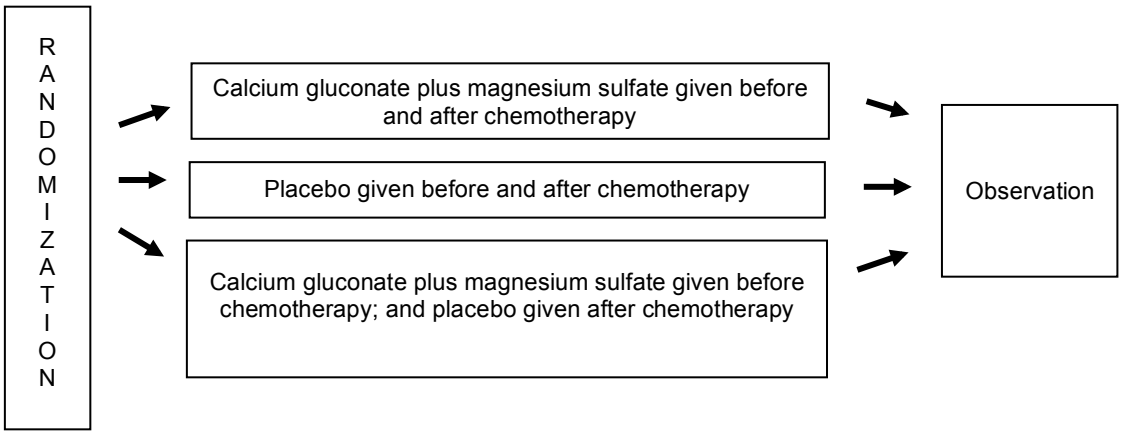
This study compared one dose to two doses of calcium and magnesium to a placebo (an inactive agent) for the prevention of a common side effect, called neuropathy (numbness and tingling), caused by the drug oxaliplatin, which is often used to treat patients with colon cancer.

The official title of this study is: NCCTG N08CB (Alliance) Phase III randomized, placebo-controlled, double-blind study of intravenous calcium/magnesium in two different versions to prevent oxaliplatin-induced sensory neurotoxicity

Why the study was done

It is well known that the chemotherapy drug, oxaliplatin, can cause side effects on nerves that result in symptoms such as sensitivity to cold or touch, pain, tingling or numbness of fingers and toes that can interfere with every day activities. In many patients, the chemotherapy has to be stopped because of these symptoms. The purpose of this study was to compare the effects, good and/or bad, of calcium and magnesium with a placebo (an inactive agent) on nerve side effects that could be caused by oxaliplatin in patients with colon cancer.

Here is a picture that explains how patients were placed into the study.



Patients were put into one of three groups by chance (randomized like the flip of a coin) to reduce differences between the groups. This was done because no one knew if one treatment was better than another. One third of the patients were given calcium and magnesium together right before and after each dose of chemotherapy; another third of the patients were given a placebo right before and after each dose of chemotherapy; and the final third of the patients were given calcium and magnesium together before each dose of chemotherapy and a placebo after each dose of chemotherapy.

This was to see if one dose of calcium and magnesium (given right before chemotherapy) was as effective as two doses of calcium and magnesium (given right before and after chemotherapy) and to see if either was better than a placebo.

Patients were given questionnaires that asked about how they were feeling and about any pain, numbness or tingling they may have been feeling. Patients were asked to complete the questionnaires each time they received chemotherapy. Their doctors also completed evaluations about their neuropathy.

When did the study start and end? The study started June 22, 2010. All patients were enrolled by June 8, 2012.

How many patients joined? 353 patients from more than 50 sites agreed to be in this study.

Study results

The study team found there were no neuropathy differences among the three study arms as measured by the questionnaires that the patients completed. Also, the study team did not find any differences using the additional measures of neuropathy that the doctors used.

What the results mean

This means that calcium and magnesium treatment does not prevent a patient from getting neuropathy, a side effect caused by oxaliplatin, a drug commonly used to treat colon cancer.

These results are for adult (over 18 years of age) patients receiving oxaliplatin as treatment for their colon cancer.

You can talk with your doctor for more information.

Scientific publications about this study

Details about the study can be found in these articles:

- Loprinzi CL, Qin R, Dakhil SR, Fehrenbacher L, Flynn KA, Atherton P, Seisler D. Phase III Randomized, Placebo-Controlled, Double-Blind Study of Intravenous Calcium/Magnesium (CaMg) to Prevent Oxaliplatin-Induced Sensory Neurotoxicity, N08CB (Alliance). *Journal of Clinical Oncology* 2013 Dec 2. [Epub ahead of print].

This sheet reviews what is known about this research study as of February 2014. New Information may be available.

This study was sponsored by the North Central Cancer Treatment Group (NCCTG), which is part of the Alliance for Clinical Trials in Oncology – a national cooperative network 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.

Research studies (or clinical trials) are done to learn what treatments work better in people than what we already have. Thank you for your interest in learning more about cancer research advances.