What this study is about

This cancer study compared two treatments to lower the amount of nausea and vomiting (getting sick to the stomach) due to cancer treatment (chemotherapy).

The full title of this study is: Phase III double-blind, placebo-controlled study of gabapentin for the prevention of delayed CINV (chemotherapy induced nausea and vomiting) in patients receiving highly emetogenic chemotherapy, NCCTG N08C3 (Alliance)

Why the study was done

Nausea and vomiting (getting sick to the stomach) are common side effects from most chemotherapy treatments. These side effects can lower the quality of patients' lives, and cause treatment delays.

Some drugs help prevent these side effects for some patients, but they do not work in all patients. Even with these drugs, about 1 of 2 people (about 50%) who are helped by these drugs still get sick to their stomachs about 2 to 6 days after getting chemotherapy treatment.

The goal of this study was to see if adding a drug called gabapentin to the common treatment would help lower the rate of nausea and vomiting 2 to 6 days after taking chemotherapy. Gabapentin is approved to control seizures, but not for the treatment of nausea or vomiting. It was chosen because other studies showed that the way gabapentin works may be similar to the way that some common anti-nausea treatments work.

Study results

These results are for cancer patients who are at least 18 years old. Patients also had to be able to move around and swallow pills.

The study found that:

- Almost 5 out of 10 patients (47%) in Group A (gabapentin) did not vomit or take more nausea and vomiting medicine 2-6 days after getting chemotherapy, compared to 4 out of 10 (41%) in Group B.
- 3 out of 10 patients (30%) vomited at some point during the study in both groups.
- About 1 out of 2 patients took more anti-nausea medicine during the 2-6 days of the study (45% in Group A and 53% in Group B).
- Patients in both groups were satisfied with the control of their symptoms. They did not feel that the quality of their daily lives was lower.

The most common serious side effects included:

- Dizziness and sleepiness in both groups.
- Side effects were the same for both groups. Overall, most patients felt better during the study.

What the results mean

This means that adding gabapentin did not help prevent or lower nausea and vomiting caused by chemotherapy treatment 2 to 6 days after taking chemotherapy. Most patients reported low levels of nausea. Most were also satisfied with the medicines used to control their sickness. 1 in 3 patients (30%) still have problems, even when treatment is used to prevent or lower these side effects.

How the study worked

Patients who got chemotherapy that was given no more than once every 8 days were asked to join this study. Before the first chemotherapy treatment, patients filled out a survey (questionnaire) about their history of nausea and vomiting. Then they were given a treatment to prevent these side effects. After the chemotherapy treatment, both groups started taking the study treatments for five days. They also wrote down if they vomited or felt sick to their stomachs in a diary. Patients then filled out other questionnaires after the study was finished.

Patients were put into 2 groups by chance (randomized) to reduce differences between the groups. This was done because no one knew if one treatment was better than another.

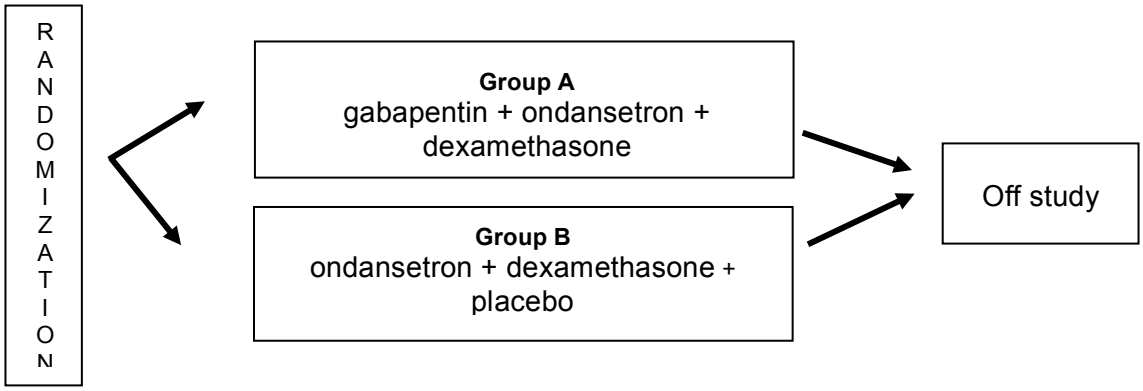
Group A received gabapentin with ondansetron and dexamethasone.
Group B got the other received ondansetron, dexamethasone and a placebo pill (no active drug).

Researchers compared patient results to a perfect result of no vomiting and no use of more medicines for nausea or vomiting for the 6 days study drugs were taken. They also measured patient satisfaction, and how daily activities were affected by these side effects.

When did the study start and end? The study started in May 2009. All patients were enrolled by February 2011.

How many patients joined? 430 patients agreed to be in this study.

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



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

Scientific publications about this study

Details about the study can be found in these articles:

- Phase III double-blind, placebo-controlled study of gabapentin for the prevention of delayed chemotherapy-induced nausea and vomiting in patients receiving highly emetogenic chemotherapy, NCCTG N08C3 (Alliance). Barton DL, Thanarajasingam G, et al. *Cancer* vol 120 (22) 3575-3583, 2014
- Can gabapentin improve control of delayed nausea and vomiting (N/V)? A phase III placebo controlled trial, N08C3 (Alliance). Barton DL, Sloan JA, et al. *Support Care Cancer* vol 21 (suppl 1) abstr 0562, 2013
- Does gabapentin prevent delayed chemotherapy-induced nausea and vomiting (N/V)? Results of a randomized placebo controlled trial, NCCTG N08C3 (Alliance). Barton DL, Sloan JA, et al. *Journal of Clinical Oncology* vol 31 (15, suppl) abstr 9513, 2013

To learn about this trial, visit the ClinicalTrials.gov website at –
http://clinicaltrials.gov/ct2/show/study/NCT00880191?term=N08C3&rank=1

This study was sponsored by the North Central Cancer Treatment Group , 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.

This summary lists what is known about this research study as of December 2014. New Information may be available.

We thank the people who joined this study and made it possible. *This study could have been completed faster if more people who had the opportunity to participate would have done so. If you know people who are offered the chance to join a cancer clinical trial, please encourage them to enroll. 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. We appreciate your advocating for federally funded research to your elected representatives.