Alliance Public Study Result Summary

What this study is about

This study compared magnesium oxide to placebo to see if it lowered hot flashes in breast cancer survivors who did not have monthly menstrual periods (menopausal).

The full title of this study is: NCCTG (Alliance) N10C2 - A double-blind, placebo-controlled study of magnesium supplements to reduce menopausal hot flashes

Why the study was done

Hot flashes are common for women who no longer have monthly menstrual periods (they are postmenopausal). Breast cancer survivors do not often get treatment for hot flashes because most hot flash treatments have hormones in them. This leads to concerns about a cancer that might return (recurrence).

Other kinds of treatment offer some help, but they also have unwanted side effects. Prior studies that used magnesium oxide (magnesia) showed promising results.

This study measured hot flash symptoms in women with a history of breast cancer. Some women were given magnesium oxide tablets and some women were given tablets with no medicine (placebo).

Study results

These results are for postmenopausal women with a history of breast cancer who had hot flashes that bothered them.

The study found that:

- All patient groups had results that were alike.

All patient groups experienced reduction in hot flash symptoms during the study treatment, but magnesium oxide was not better than placebo in reducing hot flash symptoms.

The most common serious side effects included:

- More loose bowel movements (diarrhea) with magnesium oxide (Groups 1 and 2).

What the results mean

This means that magnesium oxide does not lower hot flash symptoms in postmenopausal breast cancer survivors any more than placebo tablets.

How the study worked

Patients were placed evenly into 1 of 3 groups and received treatment for 8 weeks. All patients wrote down the number of hot flashes and how strong they were in a daily symptom diary. This started 1 week before they started taking any pills.

Group 1: 88 patients received 800 mg of magnesium oxide tablets daily.
Group 2: 91 patients received 1200 mg of magnesium oxide tablets daily
Group 3: 88 patients received placebo tablets daily.

Patients were placed into 3 groups by chance (randomized) to reduce differences between the groups. This was done because no one knew if one treatment was better than another.

When did the study start and end? The study started in December 2011. All patients were enrolled by March 2013.

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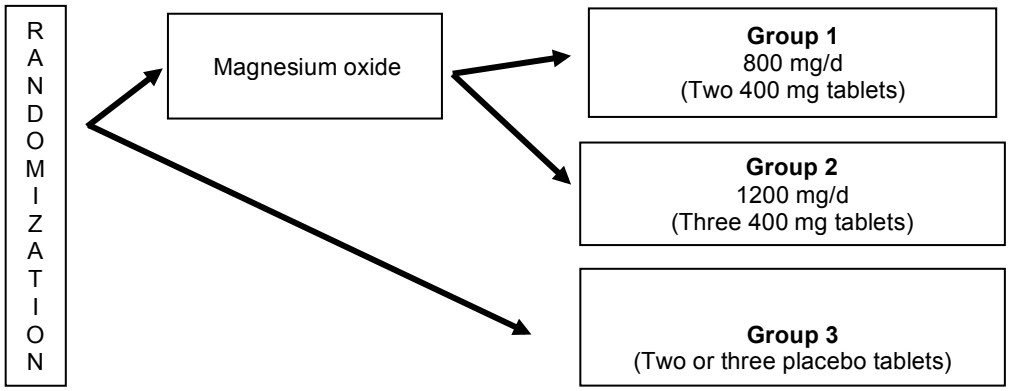
How many patients joined? 289 patients agreed to be in this study, and 267 patients received therapy.

Here is a picture that explains how patients were placed into one of 3 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:

- North Central Cancer Treatment Group N10C2 (Alliance): a double-blind placebo-controlled study of magnesium supplements to reduce menopausal hot flashes. Park H, Qin R, Smith TJ, Atherton PJ. Barton DL, Sturtz K, Dakhil SR, Anderson DM, Flynn K, Puttabasavaiah S, Le-Lindqwister NA, Padula GD, Loprinzi CL. Menopause. 2014 Nov 24. [Epub ahead of print]

To learn about this trial, visit the ClinicalTrials.gov website at –
https://clinicaltrials.gov/ct2/show/NCT01439945?term=NCCTG+N10C2&rank=1

This study was sponsored by the North Central Cancer Treatment Group, which became 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 April 2015. 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.