Alliance Public Study Result Summary

What this study is about

This cancer study compared medicine mouth rinses for people who get radiotherapy to treat head and neck cancers and who developed mouth sores from their treatment.

The full title of this study is: NCCTG N09C6 (Alliance): Randomized double-blind study of doxepin rinse versus placebo in the treatment of acute oral mucositis pain in patients receiving radiotherapy with or without chemotherapy

Why the study was done

People who are treated with radiation for head and neck cancer often get mouth sores that can lead to poor nutrition, weight loss, infection and may have to be put in the hospital.

This study was done to see if a doxepin mouth rinse would be more effective in treating mouth sore pain than to a placebo mouth rinse.

Study results

These results are for people with people with head and neck cancer and who were treated with radiation therapy.

The study found that:

The study found that the doxepin mouth rinse gave a slightly better relief from mouth and throat pain over a 4 hour time period when compared to a placebo mouth rinse.

The most common serious side effects included:

- The doxepin mouth rinse caused mild drowsiness.
- More burning and stinging was reported with doxepin during the one-minute rinse time. When given a choice, more people asked for the doxepin rinse when the study was over.

What the results mean

This means most patients found that doxepin medical mouth rinse gave longer relief from their mouth and throat pain that was caused by mouth sores from radiation therapy. These patients were willing to put up with some unpleasant mild side effects.

How the study worked

Men and women between age 18 to 60 who got radiation therapy for head and neck cancer were asked to rate their mouth or throat pain. People who had at least 4 on a scale of 0-10 were included in this study. The rating scale said 10 was the worst pain, and 0 meant no pain or numbness.

People who agreed to join this study were split 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.

People did not know if they were getting the doxepin rinse or the placebo rinse. They were asked to rate their pain and numbness at 5 minutes, 15 minutes, 30 minutes and 60 minutes after gargling and rinsing their mouths for 1 minute. The rating scale went from 0 (no pain or numbness) to 10 (the worst pain).

The next day they received the opposite rinse and reported their pain using the same rating scale.

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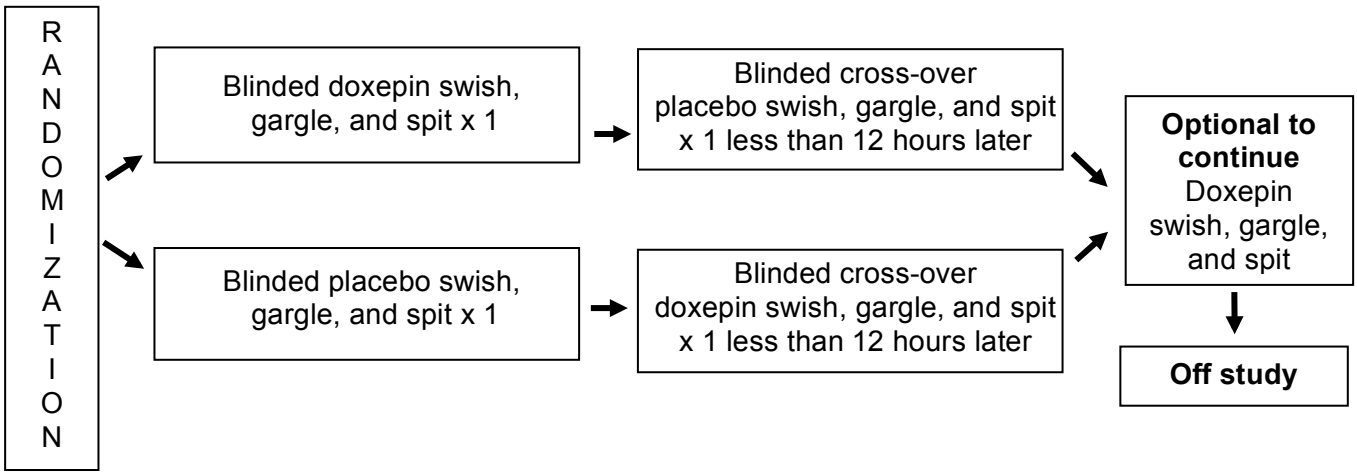
People in this study were sent home with forms to list how these mouth rinses helped their pain. People in the study also wrote down any burning and stinging or drowsiness they had when they used the mouth rinse.

This study took place at 26 cancer centers around the United States.

When did the study start and end? The study started in December 2010. All patients were enrolled by May 2012.

How many patients joined? 155 patients agreed to be in this study.

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



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:

- Doxepin Rinse Versus Placebo in the Treatment of Acute Oral Mucositis Pain in Patients Receiving Head and Neck Radiotherapy With or Without Chemotherapy: A Phase III, Randomized, Double-Blind Trial (NCCTG-N09C6 [Alliance]). Leenstra JL, Miller RC, Qin R, Martenson JA, Dornfeld KJ, Bearden JD, Puri DR, Stella PJ, Mazurczak MA, Klish MD, Novotny PJ, Foote RL, Loprinzi CL. J Clin Oncol. 2014 May 20; 32(15): 1571–1577.

To learn about this trial, visit the ClinicalTrials.gov website at https://clinicaltrials.gov/ct2/show/NCT01156142?term=N09C6&rank=1

This study was sponsored by 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 March 2015. New Information may be available.

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.

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