What this study is about

This study compared three other studies that all used the same tools to measure skin rash symptoms in patients who received treatments like radiation or targeted therapies to see how the tools compared.

The official title of this study is:
Using the Skindex-16 and Common Terminology Criteria for Adverse Events to assess rash symptoms: Results of a pooled-analysis (Alliance N0993).

Why the study was done

This study explored the way doctors rated skin rash symptoms on a form named "Common Toxicity Criteria for Adverse Events (CTCAE)" and the way patients reported skin rash symptoms on a form called "Skindex-16" to find out how they compared to each other.

Researchers looked at data (information) from three studies (Alliance N06C4, N03CB, and N05C4) that all used both forms. This study compared the scores of both forms (CTCAE and Skindex-16) to see if they measured the same kinds of skin rash symptoms. The three studies included radiation treatments or drugs called EGFR inhibitors that targeted markers used by some cancer cells to grow.

When did the study start and end? The study started in August 2009, and used data from studies that enrolled patients from December 2004 to February 2008 (N03CB from 12/17/2004 to 02/22/2008; N05C4 from 10/13/2006 to 06/13/2007; and N06C4 from 08/17/2007 to 12/07/2007).

How many patients were in the reviewed studies? Data from 412 patients were used for this analysis (128 from N03CB, 115 from N05C4, and 169 from N06C4).

Study results

Important findings: There were important differences in how doctors and patients reported skin rash symptoms on the two different forms. Doctors reported 117 minor cases of a skin rash during treatment in 259 patients who did not report any rash symptoms on the Skindex-16. There were also 855 reports of skin rash on the Skindex-16 by 392 patients, but their doctors did not report these symptoms on the CTCAE form.

What the results mean

This study shows that the CTCAE and the Skindex-16 forms each collect important information, and both should be used to measure skin rash symptoms. It also shows patients report more symptoms than doctors, and the Skindex-16 allows patients to rate added emotional and task-type burdens that the CTCAE does not measure.

These results are for adult (over 18 years of age) cancer patients who get radiation therapy or anti-EGFR drugs as treatment, and have no existing skin rash at the time of treatment.

You can talk with your doctor for more information.

Scientific publications about this study

Details about the study can be found in these articles:

- Atherton, P., K. Burger, C. Loprinzi, M. Neben Wittich, R. Miller, A. Jatoi and J. Sloan (2012). "Using the Skindex-16 and Common Terminology Criteria for Adverse Events to assess rash symptoms: results of a pooled-analysis (N0993)." *Supportive Care in Cancer* 20(8): 1729-1735. PMID: 21922203.

This sheet reviews what is known about this research study as of *03/25/2013.* 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 http://www.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.