Alliance Public Study Result Summary
NCCTG N02C4

What this study is about

This study looked at whether taking creatine supplement would increase weight and appetite in patients with weight loss caused by cancer.

The full title of this study is: Phase III double-blind, placebo-controlled randomized comparison of creatine for cancer-associated weight loss

Why the study was done

Many patients have considerable weight loss caused by cancer, which can affect how they feel and function. Previous studies have suggested that taking dietary supplements with creatine may improve the way cancer patients feel and function. The studies suggested that creatine supplements would improve muscle mass, improve strength, and in the process, decrease weight loss in cancer patients.

This study was to see if adding creatine to a cancer patient's diet would prevent weight loss.

Study results

These results are for people over 18 years of age with incurable cancers (other than brain cancer) and who have lost weight.

Patients were assigned by chance to one of two groups. This made sure that each patient had the same chance of being in any study group. Patients in the creatine group compared to the placebo group did not show any differences in:

- Weight gain/loss
- Improved appetite
- How they felt or could do activities of daily living
- Strength
- Survival

Only three patients in the study gained weight; 2 who took creatine supplements and 1 who took a placebo. This difference was not significant.

There was no difference in serious side effects when comparing the group of patients who got the creatinine supplement compared to those who got placebo. The most common serious side effects included:

- Changes in blood cells that may increase chances of infection: *1 out of 20 patients in the creatine group and 1 out of 5 patients in the placebo group.*
- Other side effects, like nausea, vomiting and shortness of breath, were seen in almost half of the patients in both groups.

What the results mean

This means that taking a creatine dietary supplement did not prevent weight loss in patients with incurable cancers who are already losing weight.

These results are important to guide future trials that will test other clinical interventions to prevent weight loss in cancer patients.

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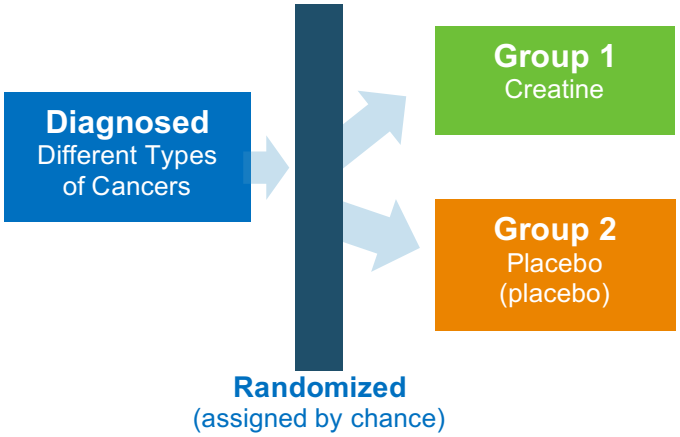
How the study worked

Patients were assigned by chance (randomized) to one of two groups. One group got the creatine supplement, the other group got a placebo. A placebo is an inactive substance that is taken the same way as the supplement, so no one knew who was taking the creatine supplement or the placebo.

To enroll in the study patients were:

- Over the age of 18 with incurable cancers (other than brain cancer)
- Expected to live longer than 3 months
- Experiencing weight loss of more than 5 pounds
- Alert and able to take medication
- Under the care of a healthcare provider

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



One group of patients received 20 grams of creatine per day (by mouth) for five days followed by 2 grams of creatine per day. The other group of patients received the same dose of placebo. Patients were weighed once a week for one month and then monthly. Patients filled out questionnaires about their appetite, strength and how they were feeling and functioning.

When did the study start and end? The study started in December 2004. All patients were enrolled by November 2007.

How many patients joined? 302 patients agreed to be in this study, and 263 completed the study.

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

Scientific publications about this study

This summary includes information in the following article:

- **A Double-Blind, Placebo-Controlled Randomized Trial of Creatine for the Cancer Anorexia/Weight Loss Syndrome (N02C4): An Alliance Trial.** Jatoi A, Steen PD, Atherton PJ, Moore DF Jr, Rowland KM Jr, Le-Lindqwister NA, Adonizio CS, Jaslowski AJ, Sloan J, Loprinzi C. Ann Oncol. 2017 May 5. doi: 10.1093/annonc/mdx232. [Epub ahead of print]

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/NCT00081250

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This study was sponsored by the Alliance for Clinical Trials in Oncology – a national clinical trial network group 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 May 2017.
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.