

## **S21. Chemoprevention of Non-Melanoma Skin Cancer: Experience with a Polyphenol from Green Tea**

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Non-melanoma skin cancer is extremely common in the United States and is increasing in incidence. Currently, the incidence in the United States of non-melanoma skin cancer is equal to or greater than all other cancers combined. In addition to primary prevention of this form of cancer through use of sun precautions, it would be extremely useful to have forms of therapy that would prevent precancerous changes from going on to form cancer, or to reverse the precancerous changes. Studies are underway to develop therapeutic agents that will fulfill these functions.

Epidemiologic evidence in humans, *in vitro* studies on human cells, and clinical experiments in animals have identified polyphenol compounds found in tea to be possibly useful in reducing the incidence of various cancers, including skin cancer.

To examine the potential for a polyphenol from green

tea, epigallocatechin gallate, to act as a chemopreventive agent for non-melanoma skin cancer, we are performing a randomized, double-blind, placebo-controlled Phase II clinical trial of topical epigallocatechin gallate in the prevention of non-melanoma skin cancer.

Study subjects with multiple pre-cancerous actinic keratoses on their forearms are randomized to apply, in a blinded fashion, epigallocatechin gallate topically to one arm and a matching placebo ointment to their other arm. The subjects are treated and followed for twelve weeks. Subjects undergo biopsies of actinic keratoses and sun-damaged skin pre and post treatment. Study endpoints are clinical and histopathologic regression of precancerous actinic keratoses, and changes in various surrogate endpoint biomarkers for the development of non-melanoma skin cancer. Study design, rationale, and preliminary results will be presented.