CLINICAL TRIAL REVIEW

Clinical Trial Review is a JDD department designed to provide physicians with information on drugs and devices undergoing clinical testing. It is our goal to inform the reader of the status of select drug and device studies relevant to the practice of dermatology before this information is available through standard channels. To participate in or learn more about these and additional trials, visit www.clinicaltrials.gov.

SKIN CANCER

A Tailored Internet Intervention to Reduce Skin Cancer Risk Behaviors Among Young Adults

Skin cancer is the most common cancer in the United States, with over a million new cases diagnosed yearly. Young adults are increasingly at risk of melanoma. Contributing to the increasing skin cancer risk is the fact that US adolescents have the lowest skin protection rates of all age groups, and also demonstrate increased exposure to natural and artificial ultraviolet (UV) radiation. Innovative interventions are needed to have an impact on skin cancer risk among young people.

Unlike previous interventions, this skin cancer risk reduction intervention will be tailored to each individual participant and delivered via the Internet. The intervention will emphasize appearance concerns, which are known to be the primary motivation for UV exposure and lack of skin protection among young adults. This will be accomplished in part through the use of personalized facial images showing UV damage, as well as computerized age progression demonstrations.

The primary aim is to examine the efficacy of a tailored intervention delivered via the Internet designed to increase skin protection and decrease sun exposure behavior among young adults at moderate to high risk of developing skin cancer. Participants will be randomized to the tailored intervention, the Skin Cancer Foundation website, or an assessment-only condition.

Condition	Intervention
Skin neoplasms	Tailored internet intervention, UV4me
Sponsor: Fox Chase Cancer Center **Collaborator:** National Cancer Institute **Study ID Numbers:** 1R01CA154928-01; 1R01CA154928 **ClinicalTrials.gov Identifier:** NCT02147080	

SKIN CANCER

Reducing Skin Cancer Risk in Childhood Cancer Survivors

The objective of this study is to determine the impact of a 12-month patient activation and education intervention on skin cancer early detection practices among childhood cancer survivors treated with radiation.

There are currently more than 420,000 Americans who are long-term survivors of childhood and adolescent cancer. While these groups have greatly benefited from recent medical advances, primarily increasing overall survival rates, treatment advances have come at a cost. It is now clear that childhood radiation therapy has caused survivors to be at extremely high risk for non-melanoma skin cancer (NMSC) and increased risk of melanoma. Early detection is crucial to reduce the morbidity caused by NMSCs, and the morbidity and mortality incurred due to melanoma. Both patient and provider action are needed to detect and treat early skin cancers and to find new solutions to ensure expedited follow-up care and treatment, especially among those who have little access to dermatologists.

To reduce skin cancers among this young and dispersed patient population, this study will address several key issues: (1) how to provide patients with the skills needed to conduct effective skin self-examinations; (2) how to prompt action from patient's physicians when worrisome moles and lesions are found; and (3) how to ensure rapid access to dermatologic exams.

Condition	Intervention
Skin neoplasms	Patient activation and education (PAE); PAE + physicial activation (MD); PAE + MD + teledermoscopy (TD).
Sponsor: Harvard School of Public Health **Collaborator:** National Cancer Institute; St. Jude Children's Research Hospital; Dana-Farber Cancer Institute; Memorial Sloan Kettering Cancer Center; Emory University. **Study ID Numbers:** 1R01CA175231; R01CA175231 **ClinicalTrials.gov Identifier:** NCT02046811	

SKIN CANCER

Topical Chemoprevention of Skin Cancer Biomarkers

Biomarkers are molecules found in the body and inside of cells. Some biomarkers are associated with specific diseases, such as skin cancer. In this research study, 2 topical medications -- diclofenac and α-difluoromethylornithine (DFMO) -- will be evaluated to test how well they prevent the development of non-melanoma skin cancers by reversing certain biomarkers in the skin.

Twenty-four male and female patients of the Dermatology Clinic at the University of Alabama at Birmingham with a history of basal cell or squamous cell carcinoma of the skin and at least 8 actinic keratoses on the upper extremities are potentially eligible for study participation.

The purpose of the study is to see if diclofenac and DFMO can be applied daily or if they need to be applied twice per day

each in order to achieve the desired results. Results from this study will help guide a second study looking at longer term use of these medications

Condition	Drug
Non-melanoma skin cancer	Topical DFMO + diclofenac
Sponsor: University of Alabama at Birmingham **Study ID Numbers:** F150814005 **ClinicalTrials.gov Identifier:** NCT02636569	

SKIN CANCER

Optical Imaging for Preoperative Delineation of Non-Melanoma Skin Cancers

The purpose of the study is to evaluate the ability and efficacy of a Polarization Enhanced Reflectance and Fluorescence System (PERFIS) for demarcation of non-melanoma skin cancer margins prior to surgery. PERFIS is a harmless and non-invasive device that has been used to image biological tissue both in vitro and in vivo. In this study it will be used to image non-melanoma skin cancer lesions prior to surgery. The use of PERFIS will not affect patient care or treatment decisions in any way. No extra tissue will be used for imaging.

If tumor margins are clear, and the PERFIS image indicates that collagen distortion lies within the pre-surgical marking of the surgeon, this would indicate that PERFIS could be useful in guiding pre-surgical marking. Alternatively, if tumor margins are positive, and PERFIS images detect collagen distortion in the area of tumor positivity such that the surgeon's pre-surgical marking would be altered to include more inconspicuous tumors, then the PERFIS analysis will be graded as successful. If tumor margins are clear, and the PERFIS image indicates the presence of collagen distortion beyond the surgeon's original marking, this would indicate failure of PERFIS to provide utility in guiding pre-surgical marking. Alternatively, if areas of the PERFIS image show distortion in both normal margins and in areas with histologically-proven tumors, then PERFIS will be graded as a failure.

Condition	Intervention
Basal cell carcinoma; squamous cell carcinoma.	PERFIS
Sponsor: Massachusetts General Hospital **Study ID Numbers:** 2015P002339 **ClinicalTrials.gov Identifier:** NCT02666833	

ECZEMA

Interferon Responses in Eczema Herpeticum

Atopic dermatitis (AD) is a chronic skin disorder characterized by recurrent viral skin infections. A small subset of patients with AD suffer from disseminated viral infections, eg, eczema herpeticum (ADEH+) after herpes simplex infection (HSV) or eczema vaccinatum after smallpox vaccination. Interferon γ (IFNγ) plays a critical role in the innate and acquired immune responses by activating macrophages, enhancing natural killer cell activation, and promoting T-cell differentiation, as well as regulating B-cell isotype switching to immunoglobulin G2a. Recent studies have demonstrated that IFNγ generation was significantly decreased after stimulation with HSV ex vivo. The purpose of this study is to determine if deficient IFNγ induction leads to susceptibility to HSV infection in ADEH+ patients. The investigators hypothesize that defective IFNγ responses in peripheral blood mononuclear cells from ADEH+ patients result from aberrant pattern recognition receptors signaling in antigen-presenting cells, resulting in low level production of interleukin-12, an essential cytokine for IFNγ generation. This study will compare results from 40 ADEH+, 40 ADEH-, and 40 non-atopic participants.

Condition	Study Type
Atopic dermatitis; eczema herpeticum; herpes simplex infections; eczema vaccinatum.	Observational
Sponsor: National Institute of Allergy and Infectious Diseases **Collaborators:** Atopic Dermatitis Research Network **Study ID Numbers:** DAIT ADRN-01 **ClinicalTrials.gov Identifier:** NCT01429311	