

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.

ATOPIC DERMATITIS

Defining the Skin and Blood Biomarkers of Pediatric Atopic Dermatitis

Atopic dermatitis (AD), also known as eczema, is the most common inflammatory skin disorder of children, affecting 10% to 20% of children and 1% to 2% of adults.

This skin disorder can be associated with unbearable itchiness and an increased susceptibility to skin infections. The cause of AD is currently poorly understood; therefore, there are no targeted treatment options at present. There have been recent studies in adults with AD that explain the cause and give new routes to investigate treatment options, but no major studies in this arena have been done in children. This study will evaluate the skin and blood biomarkers that are found in pediatric AD and compare them with adult AD.

Hypothesis: The immune system worsens the skin barrier issues that are common in atopic dermatitis. The researchers believe that there are similar immune and skin abnormalities in adult vs pediatric atopic dermatitis. Finally, blood levels of the activated molecules in atopic dermatitis can serve as surrogates for skin immune activation and will correlate with disease severity.

Condition	Intervention
Atopic dermatitis; eczema.	Observational
Sponsor: Northwestern University **Collaborator:** Rockefeller University **Study ID Numbers:** 2013-15143 **ClinicalTrials.gov Identifier:** NCT01782703	

Curing Atopic Dermatitis in Children With a Commercial Medical Device and Maintaining Healthy Skin by Using a New Cosmetic Product

This multicenter, 2-phase exploratory clinical trial will examine efficacy and safety after open-label topical administration of a medical device (Bepanthen Itch Relief Cream) for treatment of acute flare-ups, followed by topical administration of a new cosmetic bepanthen product or a cosmetic comparator in a parallel-group, randomized, investigator-blinded care phase for skin care in the remission phase in infants with mild atopic dermatitis.

Eligibility for this study includes children from 1 month to 4 years, of both sexes, with skin types 1 to 4 according to Fitzpatrick, who have mild atopic dermatitis presenting a maximum SCORAD of 25 (at screening and baseline).

Condition	Drug
Atopic dermatitis	**Bepanthen Itch Relief Cream**
Sponsor: Bayer **Other Study ID Numbers:** 17534 **ClinicalTrials.gov Identifier:** NCT02615561	

ECZEMA

Randomized Controlled Trial of an Eczema Care Plan

The objectives of this study are to increase families' understanding of eczema and to improve eczema management in the primary care setting. The researchers have created an "Eczema Care Plan" similar to those used in the management of asthma. It gives specific instructions about medications, bathing, and moisturizing, as well as when to seek further treatment. They will conduct a randomized controlled trial of the plan in Primary Care at Longwood for a 10-month period. Specifically, they aim to (1) decrease eczema severity; (2) improve patient quality of life; and (3) increase parental knowledge and confidence about eczema management. They also plan to track provider uptake and documentation of the plan, and elicit feedback from parents and providers on its use and feasibility.

Condition	Intervention
Eczema	Behavioral: Eczema Care Plan.
Sponsor: Boston Children's Hospital **Other Study ID Numbers:** ChildrensH **ClinicalTrials.gov Identifier:** NCT02251340	

DERMATOLOGIC DISEASES

Role of Angiogenesis in Dermatologic Diseases: A Potential Therapeutic Target

The researchers believe that pro-angiogenic factors are upregulated in a wide range of dermatologic diseases, including port wine stains, hemangiomas, angiofibromas, Kaposi's sarcoma, angiosarcoma, scars, rosacea, and psoriasis.

The study will consist of performing immunohistochemistry and/or microarray analysis and/or quantitative polymerase

chain reaction on previously biopsied skin specimens and newly biopsied skin specimens to evaluate the expression of various angiogenic factors in these dermatologic diseases.

In addition, some of the skin specimens may be used to make cell cultures to study expression of angiogenic factors and interactions of cells in dermatologic disease. Additionally, the researchers can use discarded human skin tissue samples from skin biopsy/surgery sites that are removed for closure but not submitted for histopathologic analysis.

Specimens collected will be processed for microarray analysis, qPCR, and/or immunohistochemistry to evaluate expression of various angiogenic factors and their receptors, including but not limited to: vascular endothelial growth factor, basic fibroblast growth factor, angiopoietin 1, angiopoietin 2, and matrix metalloproteinase.

Condition	Intervention
Dermatologic diseases	Skin tissue sample
Sponsor: University of California, Irvine **Collaborator:** Beckman Laser Institute, University of California Irvine **Other Study ID Numbers:** NIH/LAMMP-2007-6094 **ClinicalTrials.gov Identifier:** NCT00842283	

CANCER

Study of Chemotherapy-Induced Hair Changes and Alopecia, Skin Aging, and Nail Changes in Women With Non-Metastatic Breast Cancer

The purpose of this study is to see how many patients develop hair, skin, and nail changes due to cancer treatments. The investigators will study the clinical factors, genetic markers, and impact on patients' health-related quality of life (HRQoL) to learn more about who is at greater risk. The study is intended to improve understanding of how cancer patients feel about their skin, hair, and nail conditions. This information will help the researchers determine the burden on breast cancer patients and survivors. It will also help them to learn how to prevent these conditions, and it may improve the way they treat them and counsel patients.

Patients will undergo study related assessments and the appropriate HRQoL questionnaires will be administered. Baseline and follow-up clinical assessments will be performed, preferably when the patient presents to the clinic for (clinically indicated) standard-of-care visits. Initially, these visits will be coinciding with the appropriate chemotherapy dosing cycles (as applicable to select study cohorts), and subsequently they will be performed during the standard-of-care follow-up visits.

Condition	Intervention
Non-metastatic breast cancer	Clinical assessments; questionnaires; saliva sample.
Sponsor: Memorial Sloan Kettering Cancer Center **Collaborators:** University of Chicago; New York University **Other Study ID Numbers:** 15-198 **ClinicalTrials.gov Identifier:** NCT02530177	