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/ECZEMA

Efficacy of Fluocinonide Cream 0.1% (Vanos®) in Reducing Itch in Subjects With Atopic Dermatitis

The purpose of this study is to assess the efficacy and tolerability of short-term treatment with fluocinonide cream 0.1% (Vanos®) in the treatment of atopic dermatitis (AD). The hypothesis is that subjects will have a reduction in Investigator's Global Assessment scores at day 7 and day 14 compared with baseline.

Secondary objectives include the use of actigraphy monitoring to determine the ability of Vanos® cream to reduce itch, and thus nocturnal scratching, in AD. The hypothesis is that subjects will have a reduction in nocturnal scratching activity, as measured by actigraphy movement count per hour, at day 7 and day 14 compared with baseline. Other secondary outcome measures include Eczema Area and Severity Index score, Body Surface Area Involvement, Visual Analog Scale for itch, and Subject Global Assessment. The investigators hypothesize that each of these measures will be improved at day 7 and day 14 compared with baseline.

Medication adherence will be determined using objective adherence monitors. The investigators also hypothesize that subjects will have improved adherence to a topical medication for AD, compared with published sources, if they are only required to use the medication for a short and defined duration.

Condition	Drug
Atopic dermatitis	Fluocinonide cream
Sponsor: Wake Forest School of Medicine **Collaborator:** Medicis Pharmaceutical Corporation **Study ID Numbers:** 00018876 **ClinicalTrials.gov Identifier:** NCT01469767	

ATOPIC DERMATITIS/ECZEMA

Registry for the Atopic Dermatitis Research Network

People with atopic dermatitis (AD), also known as eczema, experience hot, dry, scaly skin with severe itching. In addition, people with AD are prone to skin infections and inflammation. Little is known about the causes of AD or why people with AD are more prone to infections. The purpose of this multicenter, clinical registry study is to determine genetic markers associated with susceptibility of AD patients to infections and also to serve as a potential participant database for future studies.

Participants include those with atopic dermatitis with previous or current eczema herpeticum, atopic dermatitis with previous or current eczema vaccinatum, and methicillin-resistant S. aureus. Non-Hispanic Caucasian, Non-Hispanic African American, and Mexican American populations will be targeted because they constitute the 3 largest racial/ethnic populations according to the United States Census Bureau 2009 data; however, no racial/ethnic groups will be excluded.

Condition	Study Type
Atopic dermatitis, eczema herpeticum	Observational
Sponsor: National Institute of Allergy and Infectious Diseases (NIAID) **Study ID Numbers:** DAIT ADRN-02 **ClinicalTrials.gov Identifier:** NCT01494142	

ATOPIC DERMATITIS/ECZEMA

Interferon Responses in Eczema Herpeticum (ADRN-01)

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 results from aberrant pattern recognition receptors signaling in antigen-presenting cells, resulting in low level production of IL-12, an essential cytokine for IFNγ generation. This study will compare results from 40 ADEH+, 40 ADEH-, and 40 non-atopic participants.

Study procedures will typically be completed in one visit; however, participants may be asked to return for additional unscheduled visit(s) occurring as frequently as every 3 months for the duration of the study to provide an additional blood

sample for further characterization of immune mechanisms leading to reduced IFNγ responses in ADEH+.

Condition	Study Type
Atopic Dermatitis, Eczema Herpeticum, Herpes Simplex Infections, Eczema Vaccinatum	Observational
Sponsor: National Institute of Allergy and Infectious Diseases (NIAID) **Collaborator:** Atopic Dermatitis Research Network **Study ID Numbers:** DAIT ADRN-01, NIAID Funding Mechanism **ClinicalTrials.gov Identifier:** NCT01429311	

PSORIASIS

Serum Lipid Levels and Other Biomarkers of Cardiovascular Disease in Patients With Psoriasis

Psoriasis patients are known to be at increased risk for heart disease. This may be due to the increased prevalence of cardiovascular disease risk factors in this population, including high blood pressure, diabetes, obesity, and high cholesterol. Although cholesterol levels are known to be altered in psoriasis, most studies have used standard lipid profiles to measure cholesterol. These tests indirectly measure LDL (bad cholesterol) and become less accurate when triglyceride levels are high, as often seen in individuals with psoriasis. This observational case control study has been designed to use a more specific and detailed cholesterol test to measure serum lipid levels in psoriasis patients, allowing for more accurate determination of LDL and better assessment of the lipid-contribution to cardiovascular risk.

One hundred adults of both sexes between the ages of 18 and 80 years who have a diagnosis of psoriasis as diagnosed by the principal investigator will comprise the psoriasis or case group, while controls will be selected from the same dermatology clinic. Serum lipid levels in the psoriasis patients will be evaluated compared with controls through the use of a relatively new comprehensive lipid profile test that has not been used in previous psoriasis studies.

The study will also measure other markers of inflammation that may contribute to cardiovascular disease.

Condition	Study Type
Psoriasis	Observational
Sponsor: George Washington University **Collaborator:** Name **Study ID Numbers:** IRB#100940 **ClinicalTrials.gov Identifier:** NCT01019200	

DERMATOSES

Role of Angiogenesis in Dermatologic Diseases: A Potential Therapeutic Target

The purpose of this study is to evaluate the role of angiogenesis in cutaneous disease and, ultimately, facilitate implementation of anti-angiogenic therapy in a wide range of dermatologic diseases including port wine stains, hemangiomas, angiofibromas, Kaposi's sarcoma, angiosarcoma, scars, rosacea, and psoriasis.

The researchers believe that pro-angiogenic factors are upregulated in a wide range of dermatologic diseases. Previously or newly collected biospecimens from various dermatologic diseases including those listed above will be evaluated, along with discarded human skin tissue samples from skin biopsy/surgery sites that are removed for closure but are not submitted for histopathologic analysis.

The researchers will perform immunohistochemistry and/or microarray analysis and/or quantitative polymerase chain reaction 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.

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

PUSTULAR DERMATOSIS

Anakinra for Inflammatory Pustular Skin Diseases

Inflammatory pustular skin diseases are a type of autoinflammatory disease in which the immune system attacks the body's tissues. These diseases cause painful and itchy skin rashes, eye and mouth irritation, joint pain, and fever. Several drugs for treating these diseases suppress the immune system. However, they can cause severe side effects when taken over a long period of time.

Interleukin-1 (IL-1) is a small protein that may be important in causing the inflammation seen in pustular skin disease. Anakinra is a drug that works by blocking IL-1. It has been effective in treating some inflammatory conditions such as rheumatoid arthritis. However, anakinra has not been studied for use in patients with pustular skin disease. Researchers want to see whether anakinra will be effective in treating pustular skin disease.

Participants will have an initial visit to receive the first dose of anakinra, and be shown how to give themselves daily injections of anakinra. They will then take it for up to 12 weeks,

barring any severe side effects. During this time, they will keep a study diary to record the severity of any rashes, pustules, itching, fevers, and skin or joint pain. They will bring this diary to their study visits at weeks 4, 8, and 12.

Condition	Drug
Pustular dermatosis	Anakinra
Sponsor: National Cancer Institute (NCI) **Study ID Numbers:** 130071, 13-C-0071 **ClinicalTrials.gov Identifier:** NCT01794117	