

CLINICAL TRIAL REPORT

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.

ADVANCED STAGE MELANOMA

Immunotherapy Study for Patients With Stage IV Melanoma

Sponsored by NewLink Genetics Corporation, the main objective of this study is to determine the safety and clinical response rate of the administration of ipilimumab with or without HyperAcute® Melanoma (HAM) immunotherapy for patients with stage IV, metastatic melanoma.

Despite the best clinical efforts and breakthroughs in biotechnology, most patients diagnosed with advanced stage melanoma continue to die from their disease. Resistance to one type of chemotherapy often rapidly leads to resistance to many other chemotherapy drugs. These major causes of cancer progression are usually discussed when considering treatment options for patients with a disease that continues to grow and spread. However, another important part of the body should also be considered – the immune system. This human clinical trial proposes a new way to make the immune system recognize the cancer cells, and encourages it to attack and destroy them.

Patients who have known stage IV, metastatic melanoma who have known stage IV, metastatic melanoma are given 4 injections of ipilimumab 3 weeks apart x 4 injections with or without HAM immunotherapy. The investigators hypothesize that compared with the use of ipilimumab alone, this form of combinatorial immunotherapy will result in tumor stabilization or shrinkage, as well as a significant prolongation of progression-free, disease-free, or overall survival.

Condition	Intervention
Metastatic melanoma	**Drugs:** HyperAcute®-Melanoma (HAM) Immunotherapy and ipilimumab
Study ID Numbers: NLG0304, 1303-1217 **ClinicalTrials.gov Identifier:** NCT02054520	

SKIN OF COLOR CLINICS

Black Patients' Lived Experiences and Perceptions of Skin of Color Clinics

Across the USA, Skin of Color (SOC) clinics have been established with the goal of providing medical care and supporting research related to patients with skin of color. There have been no formal studies evaluating why patients seek medical care at SOC clinics, or treatment outcomes. Reasons may include past experiences with other providers, the perception that providers working in these clinics have a special interest or knowledge in caring for patients with skin of color, the expectation of cultural sensitivity, the hope that their provider may have a similar ethnic background, and/or ease of communication with their provider. Through focus group discussions, the study aims to identify the factors influencing a patient's choice to seek medical care at a SOC clinic and to gain insight into the presence and impact of racial concordance between provider and patient. The current study will focus on self-identified African American patients, with an interest in conducting similar sessions with patients of other ethnicities and races in the future.

Transcripts of focus group discussions will be transcribed and then analyzed via a "long-hand" inductive approach by 2 dermatologists and 1 psychologist. For each of the 8 posed focus group questions, the reviewers will independently induce a common thematic response.

Sponsor	Collaborator
Northwestern University	**University of Wisconsin-Stout**
Study ID Numbers: SSLP100114 **ClinicalTrials.gov Identifier:** NCT02375659	

ACNE VULGARIS

CD5789 Long Term Safety Study on Acne Vulgaris

This is a multi-center, open-label, non-comparative safety and efficacy study with 52 weeks of treatment on the face and trunk for acne vulgaris. Its purpose is to determine the safety and efficacy of CD5789 50 µg/g cream in the long-term treatment of subjects with acne vulgaris. Efficacy will be evaluated as a secondary objective. Assessment of local tolerability and adverse events will be assessed at each visit in a timeframe of up to 52 weeks.

To be included in the study, the subject must have a facial acne severity grade of IGA grade 3 (moderate) and a minimum of 20 inflammatory lesions and 25 non-inflammatory lesions at screening and baseline visits. Alternatively, he/she must

have truncal acne severity of PGA grade 3 (moderate) and a minimum of 20 inflammatory lesions and 20 non-inflammatory lesions on the shoulders, anterior chest, and upper back at screening and baseline visits.

Condition	Intervention
Acne vulgaris	**Drug:** CD5789
Sponsor: Galderma R&D **Study ID Numbers:** RD.06.SPR.18250 **ClinicalTrials.gov Identifier:** NCT02189629	

PLAQUE PSORIASIS

DFD06 Cream vs Comp01 Cream HPA Axis Suppression Study in Patients With Moderate to Severe Plaque Psoriasis

This is a randomized, parallel group, open label study whose purpose is to assess the potential for adrenal suppression and systemic drug absorption following multiple dosing with DFD06 cream vs Comp01 cream in subjects with moderate to severe plaque psoriasis. This study will evaluate the potential of DFD06 cream to suppress the hypothalamic-pituitary-adrenal (HPA) axis as compared with Comp01 cream when applied twice daily for 15 days.

Subjects must present with a clinical diagnosis of stable (at least 3 months) plaque psoriasis. They must have psoriasis involving 20% to 50% body surface area, not including the face, scalp, groin, axillae, and other intertriginous areas. They must have an IGA grade of at least 3 (moderate) at the baseline visit.

Condition	Intervention
Plaque psoriasis	**Drug:** DFD06 cream and Comp01 cream
Sponsor: Promius Pharma, LLC **Study ID Numbers:** DFD06-CD-007 **ClinicalTrials.gov Identifier:** NCT02131324	

MALIGNANT SKIN NEOPLASM

Website Application Based Education and Text Messaging in Improving Skin Wound Care in Patients Undergoing Mohs Surgery

This randomized clinical trial will study how well website application–based education and text messaging works in improving skin wound care in patients undergoing Mohs surgery (a surgical procedure used to treat skin cancer). Website application and text messaging–based education may help patients stick to wound care instructions before and after surgery and lower their anxiety levels, as well as help monitor their activity.

The condition is malignant skin neoplasm and the interventions consist of Mohs surgery, internet-based intervention, telephone-based intervention, educational intervention, and exercise intervention. Patients are randomized to 1 of 4 groups: group 1 (video, text message); group 2 (educational video); group 3 (text message); and group 4 (control). The primary objective is to create a web application that will educate dermatologic surgery patients prior to their operations with educational videos. A secondary objective is to create and evaluate a web-based system to send wound care instructions to patients by text message after their operation.

Condition	Intervention
Malignant skin neoplasm	**Mohs Surgery**
Sponsor: Comprehensive Cancer Center of Wake Forest University **Collaborator:** National Cancer Institute (NCI) **Study ID Numbers:** CCCWFU 01714, NCI-2015-00217, CCCWFU 01714, P30CA012197 **ClinicalTrials.gov Identifier:** NCT02373722	

ATOPIC DERMATITIS

Bleach Bath Treatment of Adults With Atopic Dermatitis

This is pilot, mechanistic study to address whether bleach baths given to adult subjects with atopic dermatitis or eczema, who are colonized with the bacteria *Staphylococcus aureus*, will significantly alter their skin microbiome and in so doing improve their skin barrier, diminish expression of inflammatory proteins in the skin, and improve itch. To answer these questions the investigators will perform a 3-month, pilot, investigator-initiated, single-center, open-label clinical study allowing us to test the following hypothesis: 1) that bleach baths will normalize skin barrier function; 2) that bleach baths will diminish the local inflammatory response in the skin; and 3) that bleach baths will improve validated measures of itch (also called pruritus).

Studies have demonstrated a remarkable clinical improvement in atopic dermatitis subjects who take bleach baths 2 times per week for 3 months. However, the mechanism by which these bleach baths improve the disease remains entirely unknown. This study will assess the effects bleach baths have on bacteria that can and cannot be cultured using new molecular biologic tools that have shown us that the skin is home to thousands of different microbial species. The investigators will also determine whether bleach baths affect skin barrier integrity and the cutaneous expression of lymphocyte-derived cytokines that are thought to cause the skin inflammation in subjects with atopic dermatitis.

Condition	Intervention
Atopic dermatitis	**Bleach bath (sodium hypochlorite)**
Sponsor: University of Rochester **Collaborator:** National Institutes of Health (NIH) and National Eczema Association **Study ID Numbers:** BB/URMC-2013 **ClinicalTrials.gov Identifier:** NCT01996150	