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.

ACNE SCARS

Effect of Multiple Subcisions on Rolling Acne Scars

Sponsored by Northwestern University, the purpose of this pilot study is to find out whether the use of multiple subcisions over several visits will improve the appearance of rolling acne scars compared with no treatment. The change in acne scarring is measured using a quantitative global scarring grading system to compare baseline with the treatment. To be included in the study, subjects must have bilateral rolling acne scars on each side of their face, and no active or ongoing acne.

Subjects will receive multiple subcision treatments to their randomized side of the face 5 times in total, spaced 4 weeks apart. At the start of the procedure, a straight vitrectomy knife will be inserted subdermally and slowly advanced parallel to the dermis. Rapid advancement and retraction of the needle under the scarred area in a lancing motion will be performed to abrade the underside of the dermis, followed by side to side sweeping motions attempting to break any fibrous attachments to the deeper tissues. Control subjects will receive no intervention control on the other side of the face.

Condition	Intervention
Acne scarring	Multiple subcision
Sponsor: Northwestern University **Responsible Party:** Murad Alam, Professor in Dermatology, Otolaryngology-Head and Neck Surgery, and Surgery, Northwestern University **Study ID Numbers:** STU97928 **ClinicalTrials.gov Identifier:** NCT02216864	

TINEA CORPORIS

An Open Label Pharmacokinetic Study of Naftin for Tinea Corporis

This open label, multi-center, multi-application pharmacokinetic study in pediatric subjects with tinea corporis is designed to quantify the plasma concentration of single and multiple dose of naftifine hydrochloride cream, 2%, in pediatric subjects with tinea corporis over a time frame of 2 weeks.

For the younger pediatric cohort, aged 2 years to 5 years 11 months, approximately 3 grams of Naftin® Cream, 2% will be applied once per day. For the older pediatric cohort, aged 6 years to 11 years, 11 months, approximately 4 grams of Naftin® Cream, 2% will be applied once per day.

Inclusion criteria include the presence of tinea corporis, characterized by clinical evidence of a tinea infection at multiple sites covering a total of at least 1% body surface area. Exclusion criteria include tinea infection of the scalp, face, groin, and/or feet, as well as any life-threatening condition within the last 6 months.

Condition	Intervention
Tinea Corporis	**Drug:** Naftin® Cream, 2%
Sponsor: Merz Pharmaceuticals, LLC **Study ID Numbers:** MUS90200_4025_1 **ClinicalTrials.gov Identifier:** NCT02466867	

VASCULAR LESIONS

VELOS for the Treatment of Vascular Lesions and Skin Rejuvenation

This is a multi-center, multi-cohort, prospective, open-label study of VELOS for the treatment of vascular skin disorders. The plan is to enroll up to 60 subjects from up to 3 centers in the US and worldwide. It will include treatment of facial skin disorders, leg veins, skin rejuvenation, and skin laxity.

The primary objective of this trial is to collect data from the use of VELOS in clinical practice under a wide range of treatment parameters variability, including RF energy and laser pulse duration for treating each of the vascular disorders. This will be conducted by documenting the physician-selected treatment parameters, as well as the subjects' clinical clearing response, perception of improvement, and sensations, through the study treatments and post-treatment(s) follow-up visits.

Condition	Intervention
Vascular lesions and photoaging	**Device:** Pulsed dye laser/bipolar radiofrequency (Velos)
Sponsor: Syneron Medical **Study ID Numbers:** IH149901 **ClinicalTrials.gov Identifier:** NCT02468453	

MYCOSIS FUNGOIDES

Stem Cell Transplant Therapy With Campath-1H for Treating Advanced Mycosis Fungoides and Sezary Syndrome

Mycosis fungoides (MF) and its leukemic variant Sezary syndrome (SS) are the most prevalent forms of CTCL. While early stage MF is restricted to patches and plaques involving the skin, most patients eventually develop cutaneous tumors, generalized erythroderma, or dissemination to peripheral blood, lymph nodes, or visceral organs. Currently existing therapy of tumor-stage and disseminated CTCL is palliative, with most patients dying within 1-5 years.

This study will investigate the safety and effectiveness of a modified donor stem cell transplantation procedure for treating advanced MF and SS. Patients with advanced MF or SS who are between 18 and 70 years of age and have a matched family donor 18 years of age or older may be eligible for this study. Stem cells will be collected from both the patient and donor. To do this, the hormone G-CSF will be injected under the skin for several days to push stem cells out of the bone marrow into the bloodstream. Then, the stem cells will be collected by apheresis. The anticipated hospital stay is 3 to 4 days, when the first 3 doses of Campath will be monitored for drug side effects. The rest of the procedures, including the transplant, can be done on an outpatient basis.

Condition	Intervention
Mycosis Fungoides and Sezary Syndrome	**Drug:** Campath-1H
Sponsor: National Heart, Lung, and Blood Institute (NHLBI) **Study ID Numbers:** 020250, 02-H-0250 **ClinicalTrials.gov Identifier:** NCT00047060	

INFANTILE HEMANGIOMA

Timolol for the Prevention of Proliferation of Infantile Hemangioma (TiPPIH Trial)

The purpose of this trial is to see if a topical beta blocker is effective in preventing the proliferation of infantile hemangioma. Infantile hemangiomas (IH) are among the most common, benign vascular tumors of infancy with an estimated prevalence of 4% to 5% of the population. IH are not found at birth but become evident within the first few weeks of life. Although frequently thought of as benign lesions, hemangiomas can occur in locations to cause functional impairment of vital organs, can lead to ulcerations, scarring, or disfigurement, and can lead to life-threatening complications.

For periorbital lesions that may cause amblyopia or anisometropia, topical Timolol has been reported to be of benefit. The investigators find it reasonable to start treatment with a topical beta blocker at an early stage of hemangioma to prevent the growth and proliferation and hence the possible severe effects associated with growth and thus impairment of vital organs/tissues. The advantage of a topical therapy is the decreased risk of systemic side effects compared with oral or intravenous administration. The disadvantage is that limited penetration may preclude effectiveness for the thicker or deeper lesions.

Condition	Intervention
Infantile Hemangioma	**Drug:** Topical 0.5% Timolol
Sponsor: Alice K. Gong, The University of Texas Health Science Center at San Antonio **Study ID Numbers:** HSC20110333H **ClinicalTrials.gov Identifier:** NCT01434849	

UNWANTED TATTOOS

Laser Treatment of Tattoos With Pico Laser

The purpose of this multicenter study is to determine whether Pico laser is effective and safe in the treatment of unwanted tattoos. The Investigational device is a dual wavelength laser system developed for treatment of pigmented lesions and for tattoo removal. The base unit is a GentleMax Pro laser system modified to emit light at wavelengths of 532 and 1064 nm and deliver pulse energy up to 400mJ, and pulse duration of 700 ps.

Three months after the final treatment, the global percentage of tattoo clearance will be evaluated by blinded observers using post-treatment photographs compared with baseline photographs. The average number of treatments will be determined in order to obtain 50% and 75% tattoo clearance. Rate of clearance will be assessed globally, independent of tattoo color and based on individual colors. Adverse events will be evaluated immediately after and before each subsequent laser treatment, and will be based on the incidence and severity of side effects caused by the laser treatments.

Condition	Intervention
Unwanted tattoos	**Device:** Picosecond Laser system
Sponsor: Syneron Medical **Study ID Numbers:** IH132802 **ClinicalTrials.gov Identifier:** NCT02146807	