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.

VITILIGO

Photocil (Topical) for the Treatment of Vitiligo

Narrow Band Ultraviolet B (NB-UVB) phototherapy is a common treatment for patients with psoriasis, and has been reported to be safe and effective in numerous clinical trials. Photocil is a topical drug (cream) that selectively delivers NB-UVB therapy when exposed to sunlight. Photocil is intended to help protect users from non-therapeutic UVB radiation while selectively passing wavelengths of light in the NB-UVB range with peak transmission of 308 nm. The aim of the study is to assess the safety and efficacy of Photocil in the treatment of vitiligo.

The strict treatment regimen of traditional NB-UVB phototherapy – 2 to 3 sessions per week for an average of 12 weeks or more, performed at a specialized phototherapy clinic, combined with high cost and little to no reimbursement – make compliance and access a major drawback.

In order to address these drawbacks of traditional phototherapy, we developed a novel topical cream – Photocil – that selectively delivers NB-UVB therapy when exposed to sunlight. When used with natural sunlight, Photocil provides a convenient alternative to traditional clinic-based phototherapy, and therefore has the potential to dramatically increase patient compliance and treatment outcome.

Condition	Intervention
Vitiligo	Photocil for vitiligo
Sponsor: Applied Biology, Inc. **Study ID Numbers:** AB-DRUG-PHOTOCIL-VT-001 **ClinicalTrials.gov Identifier:** NCT01992185	

ALOPECIA

Intralesional Steroids in the Treatment of Alopecia Areata

Alopecia areata is a common form of hair loss that reportedly occurs in up to 1.7% of the population at some time in their life. It is apparently triggered when the individual's own immune system attacks hair follicles on the scalp or body, resulting in hair loss ranging from single patches on the scalp (patch type alopecia areata) to loss of every hair on the scalp and body (alopecia universalis). Currently, there are limited treatment options for alopecia areata and, unfortunately, the treatments used have never been rigorously tested in a placebo-controlled trial.

Triamcinolone (kenalog) is a steroid solution that has been used as treatment for alopecia areata for over 50 years. It is administered via injection into the scalp and appears to have some efficacy for patients with mild to moderate alopecia areata. We currently do not have objective data on the frequency of occurrence of successful regrowth, the duration of response, or the incidence of side effects. In addition, there is disagreement between clinicians regarding the dose of intralesional triamcinolone (IL TAC) that is considered most effective.

This study aims to determine the frequency of response to treatment with 3 concentrations of IL TAC: 2.5 mg/mL, 5 mg/mL, or 10 mg/mL; as well as the duration of response and incidence of side effects compared with treatment with placebo (sterile saline solution).

Condition	Intervention
Alopecia areata	**Drug:** Triamcinolone
Sponsor: Columbia University **Collaborator:** Clinical and Translational Science Institute, University of Minnesota **Study ID Numbers:** AAAI5852 **ClinicalTrials.gov Identifier:** NCT01898806	

VOLUME LOSS TO DORSUM AREAS OF HANDS

A Single-Center Investigator-Initiated Evaluator-Bilateral-Comparison Pilot Study of Injectable Calcium Hydroxylapatite With and Without Triamcinolone Acetate for the Treatment of Volume Loss to Dorsum Areas of the Hands

This is a single-center, investigator-initiated, double-blinded, randomized, bilateral-comparison pilot study of injectable calcium hydroxylapatite with and without triamcinolone acetate for the treatment of volume loss to the dorsum areas of the hands. The primary analyses of efficacy will be based on the change from baseline through day 360 for assessment (based on the Merz Validated Hand Grading Score).

The study start date was May 2015 and the estimated study completion date is August 2016. The active comparator will be an injection of calcium hydroxylapatite with triamcinolone acetate, and the placebo comparator will be a placebo injection of calcium hydroxylapatite with a placebo.

Subjects must have cutaneous and soft tissue atrophy in the dorsum of both hands, as indicated by the Merz Validated Hand Grading Scale, with a score of 2, 3, or 4. Subjects must also be planning a re-volumizing rejuvenation treatment to the dorsum area of both hands

Condition	Intervention
Volume loss to dorsum area of hands	Calcium hydroxylapatite and triamcinolone acetate
Sponsor: Goldman, Butterwick, Fitzpatrick and Groff **Collaborator:** Merz Pharmaceuticals, LLC **Study ID Numbers:** RAD-2010 **ClinicalTrials.gov Identifier:** NCT02454088	

ONYCHOMYCOSIS

Pulsed Dye Laser Treatment of Onychomycosis

The purpose of this research is to investigate the use of the Candela V-Beam Pulsed Dye Laser for the treatment of onychomycosis, a common nail fungus. The hypothesis is that complete nail clearance will occur in approximately half of the patients after 3 laser treatments.

Ten patients will participate nationally, all enrolled at Jefferson. Involvement in the study will last about 8 to 12 weeks per subject, the entire study taking about 12 months to complete. Subjects must have a diagnosis of onychomycosis based on a positive fungal culture for dermatophyte and positive periodic acid schiff from toenail clippings. Excluded from the study is anyone with HIV/immunosuppression, candidal toenail infection, and prior antifungal therapy within the last 6 months; as well as anyone with a personal history of psoriasis, lichen planus, or significant photosensitivity disorder.

Condition	Intervention
Onychomycosis	Pulsed dye laser for the treatment of nail fungus
Sponsor: Thomas Jefferson University **Study ID Numbers:** IRB 13D.230 **ClinicalTrials.gov Identifier:** NCT01915355	

CHEMICAL PEELS/MELASMA

A Pilot Study Testing Salicylic Acid Peels Vs Glycolic Acid Peels for the Treatment of Melasma

Salicylic acid and glycolic acid chemical peels are skin treatments used to correct uneven texture and color by removing dead cells from the skin's top layer. The purpose of this study is to discover the safety and effectiveness of salicylic acid chemical peels compared with glycolic acid chemical peels for the treatment of melasma.

Participants in this study will be patients who are clinically diagnosed with at least a 2 cm x 2 cm patch of melasma on each side of their face (forehead or cheek). One half of the subject's face will be randomly selected to receive 4 treatments of 30% glycolic acid peels, and the other half of the face will receive 4 treatments of 30% salicylic acid peels, all at weeks 0, 4, 8, and 12. The follow-up visit will be at week 16. This study is a pilot study designed to determine feasibility of these procedures.

A dermatologist will blindly evaluate the treated areas of each half of the face at baseline and at the final follow-up visit (week 16), comparing the areas treated with salicylic acid chemical peels with those treated by glycolic acid chemical peels to determine the best overall cosmetic appearance.

Condition	Intervention
Melanosis	Salicylic acid peels, glycolic acid peels
Sponsor: Northwestern University **Study ID Numbers:** STU84250 **ClinicalTrials.gov Identifier:** NCT01976286	

SCAR CARE

Survey Study for Pain Management, Wound Care, Scar Care, or Urinary Drug Testing

This is a survey study that will be given to patients who have been prescribed a topical compound for pain management, wound care, or scar care; or to patients who have been requested to do a urinary drug test (UDT) by their provider.

The initial survey for pain management, wound care, scar care, or UDT will be given to the patient by their providers during their office visit. Follow-up surveys will be given at 30, 60, and 90 days. These surveys will be collected by e-mail or follow-up calls from Datum Research, LLC. Data collection for this study will be derived through these surveys, and the prescription written by the provider. Primary outcome measures are changes in pain, scar care, wound care, and UDT survey results. Rahm Foundation will continue the study until sufficient information has accumulated to meet the scientific objectives of the study (ie, numeric targets or effect size); the feasibility of collecting sufficient information diminishes to unacceptable levels, poor enrollment, loss to follow-up; and/or other methods of gathering appropriate information become achievable or are deemed preferable.

Condition
Pain, scars, wounds, urinary drug testing
Sponsor: Rahm Foundation **Collaborator:** Datum Research, LLC **Study ID Numbers:** RAHM 1001 **ClinicalTrials.gov Identifier:** NCT02195063