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

The Use of Bellafill for Atrophic Acne Scar Correction in the Full Facial Area

This is an open-label, multicenter, prospective pilot study assessing the efficacy and safety of Bellafill for the correction of distensible atrophic acne scars in the full facial area. All enrolled subjects will receive initial treatment with Bellafill, as well as touch-up treatments (if necessary to achieve optimal correction). Subjects will be evaluated at screening (minus one month), baseline (day 0), month 1, month 4, and month 7.

Correctable acne scars will be individually identified, and only scars that the investigator determines to be correctable will receive study treatment. All eligible scars within the treatment area will be treated. Bellafill will be injected using a standard tunneling technique whereby the filler is injected in a retrograde manner using several passes until the scar reaches a desired level of correction. A touch-up treatment is allowed if additional treatment is required to achieve optimal correction.

Subjects will be male or female outpatients of any race, 21 years of age or older. Female subjects of childbearing potential must have a negative urine pregnancy test result at baseline and practice a reliable method of contraception throughout the study. All subjects must have the presence of ≥ 4 distensible atrophic acne scars (treatment scars) in in the facial area.

Condition	Intervention
Atrophic acne scarring	Bellafill
Sponsor: Suneva Medical, Inc. **Collaborator:** Ethica Clinical Research Inc. **Study ID Numbers:** SUN-1504 **ClinicalTrials.gov Identifier:** NCT02642627	

ACNE

SkinPen Efficacy on Acne Scars on the Face and/or Back

This single-center, clinical trial will take place over a 90-day course followed by visits at month 1 and month 6 post-treatment to assess the efficacy and tolerability of the SkinPen device when used on both men and women on the face and/or back.

At least 20 subjects of varying Fitzpatrick skin types will be admitted to the trial for treatment on their moderate to severe acne scars on the face and/or back. Implementation of needle depths ranging from 0.25 mm to 2.0 mm will depend on the severity of the scars and their location. Each subject will undergo 3 treatments in 30-day increments, and pre-treatment images, as well as month 1 and month 6 post-treatment images, will be taken. Assessment will be based on the Goodman and Baron's grading system, the Clinician's Global Aesthetic Improvement Scale, and a self-assessment.

Included are men and women 18 to 60 years of age, in good health, with approximately 5 to 10 atrophic acne scars of mixed types (boxcar and/or rolling scars with some icepick scars allowed) on their face and/or back that are moderate to severe.

Condition	Intervention
Atrophic acne scar	SkinPen
Sponsor: Bellus Medical, LLC **Study ID Numbers:** Bellmed001 **ClinicalTrials.gov Identifier:** NCT02646917	

PSORIASIS

A Case Control Study Evaluating the Prevalence of Non-Alcoholic Fatty Liver Disease Among Patients With Psoriasis

Psoriasis is a common inflammatory disorder of the skin and, in some patients, the joints. The main objectives of this trial are to establish the association of psoriasis and the presence of non-alcoholic fatty liver disease (NAFLD) in patients with psoriasis. NAFLD is the accumulation of fat vacuoles in the cytoplasm of hepatocytes and is believed to be the most common cause of chronic liver disease in developed countries. Currently, the metabolic syndrome (MS) has been found to be a strong predictor of NAFLD, and NAFLD is widely accepted to be the hepatic manifestation of MS. MS is a cluster of diabetes mellitus, hypertension, visceral obesity, and hyperlipidemia and is thought to be caused by insulin resistance and the presence of a systemic inflammation, which is evidenced by the increased level of inflammatory cytokines such as TNF in this group of patients. This is a case control study of patients who attend the dermatologic clinic at George Washington University (GWU) with a clinical diagnosis of psoriasis. By performing a limited RUQ abdominal ultrasonography at GWU hospital, patients with a possible diagnosis of NAFLD will be screened. Since NAFLD is a diagnosis of exclusion, those patients who have been

screened positive for NAFLD will be further evaluated for ruling out the other etiologies of fatty liver such as alcohol abuse and hepatitis.

Condition	Study Type
Psoriasis, non-alcoholic fatty liver disease	Observational
Sponsor: George Washington University **Study ID Numbers:** IRB# 030940 **ClinicalTrials.gov Identifier:** NCT00930384	

PSORIASIS

Icotinib Hydrochloride Cream in Healthy Adults and Psoriasis Patients

This is a phase 1 study to evaluate the safety, tolerability, and pharmacokinetics of icotinib hydrochloride cream in healthy adults and patients with mild to moderate psoriasis.

Icotinib hydrochloride is a small-molecule epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor, which has been approved for the treatment of advanced non-small-cell lung cancer (NSCLC) in China in its oral form. As EGFR is implicated in the pathogenesis of psoriasis, icotinib hydrochloride is being developed as a cream for the treatment of mild-to-moderate psoriasis.

This is a single-center, randomized, double-blind, placebo-controlled study of icotinib hydrochloride cream by topical administration. The study is designed in 2 parts: in healthy subjects (phase 1) followed by patients with mild to moderate psoriasis (phase 2). One percent and 2% icotinib hydrochloride cream will be initially applied to healthy subjects. Once the study in healthy adults shows favorable safety and tolerability, a study in patients with mild-to-moderate psoriasis will follow. Approximately 28 subjects will be enrolled, including 12 healthy subjects (phase 1) and 16 patients with psoriasis (phase 2).

Condition	Drug
Psoriasis	1% icotinib hydrochloride cream; 2% icotinib hydrochloride cream; placebo.
Sponsor: Betta Pharmaceuticals Co., Ltd. **Collaborator:** Quintiles, Inc. **Study ID Numbers:** BD-ICC-NZ-I01 **ClinicalTrials.gov Identifier:** NCT02574091	

MELANOMA

Neoadjuvant and Adjuvant Checkpoint Blockade in Patients With Clinical Stage III or Oligometastatic Stage IV Melanoma

The goal of this clinical research study is to learn if giving nivolumab alone or in combination with ipilimumab before and after surgery can help to control metastatic melanoma. The safety of these drugs will also be studied.

Patients must have histologically or cytologically confirmed stage 3 B/C or stage 4 oligometastatic melanoma. Oligometastatic melanoma is defined as 3 or fewer areas of resectable disease, excluding central nervous system and bone involvement. Patients with cutaneous, mucosal, acral, ocular, or unknown primary melanomas are eligible for enrollment. For patients with stage 4 disease with distant lymph nodes, a maximum of 3 separate lymph node sites fit the definition of oligometastatic disease. Resectable tumors are defined as having no significant vascular, neural, or bony involvement. Only cases where a complete surgical resection with tumor-free margins can safely be achieved are defined as resectable.

Eligible patients will be randomly assigned to 1 of 2 study groups. Group A will receive nivolumab by vein every 2 weeks for a total of 4 doses, and then have surgery. After that, they will receive nivolumab for an additional 6 months. Group B will receive nivolumab and ipilimumab by vein every 3 weeks for 3 doses, and then have surgery. After that, they will receive nivolumab alone for 6 months.

Condition	Drug
Melanoma; oligometastatic melanoma.	Nivolumab 1 mg/kg; ipilimumab; nivolumab 3 mg/kg.
Sponsor: M.D. Anderson Cancer Center **Collaborator:** Bristol-Myers Squibb **Study ID Numbers:** 2015-0041 NCI-2015-01520 **ClinicalTrials.gov Identifier:** NCT02519322	