

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.

ROSACEA

Genetic Basis of Rosacea Study

Rosacea is a common disease characterized by inflammation and vascular abnormalities of the facial skin and ocular surface. It it considered to be a syndrome encompassing various combinations of cutaneous signs, including flushing, erythema, telangiectasia, papules, edema, ocular lesions, and rhinophyma. The exact etiology of cutaneous rosacea is unknown, but it is characterized by persistent vasodilation, increased vascular permeability, and vascular hyper-reactivity of the microcirculation of the central part of the face. The purpose of this study is to develop gene expression profiles of papulopustular rosacea compared with those of normal skin. The investigator hopes to better understand the abnormal gene functions that might contribute to this condition. This understanding may lead to the development of additional and better treatments for rosacea.

Condition	Intervention
Rosacea	Skin biopsy
Sponsor: Stanford University **Study ID Numbers:** 22419 **ClinicalTrials.gov Identifier:** NCT02749786	

Photodynamic Therapy for Papulopustular Rosacea

Topical therapy is not always effective in treating symptoms of rosacea. Furthermore, rapid recurrence is common following the use of systemic antibiotics, resulting in the chronic use of these medications to control the disease. Although the exact pathogenesis of rosacea is unknown, treatment for this condition has been investigated based on its similarity to acne and photodamaged skin. Case reports have shown promising results in rosacea patients treated with methyl aminolevulinate photodynamic therapy (MAL-PDT). Other than a case report which observed significant improvement of papules, pustules, erythema, and flushing following 5 - aminolevulinic acid photodynamic therapy (ALA-PDT) treatment of a patient with rosacea, the role of ALA-PDT in the treatment of rosacea has not been reported.

This pilot study is investigating the efficacy of ALA-PDT in treating papulopustular rosacea. The objectives of the study are as follows:

- To evaluate improvement of the inflammatory lesions (papules, pustules, nodules), erythema, and telangiectasia of rosacea as assessed by the Investigator's Global Assessment.
- To evaluate improvement of the inflammatory lesions of rosacea as assessed by the Inflammatory Lesion Investigator's Global Assessment.

Condition	Intervention
Rosacea; papulopustular rosacea.	Aminolevulinic acid topical solution 20%; Blu-U Light Therapy.
Sponsor: George Washington University **Collaborator:** DUSA Pharmaceuticals, Inc.. **Study ID Numbers:** 031416 **ClinicalTrials.gov Identifier:** NCT02075671	

Internet Surveys and Their Impact on Adherence to Brimonidine Topical Gel and Quality of Life in Patients With Rosacea

An investigator-blinded, prospective, 6-month study of subjects with persistent erythema associated with active rosacea will be conducted in 20 subjects aged 18 years and older. All subjects will receive standard-of-care brimonidine topical gel, 0.33% with instructions to apply it once daily per package insert. Adherence will be assessed using weekly internet surveys to document how often the medication is being used, as well as reminders about rosacea triggers and general use of brimonidine.

Subjects with persistent erythema associated with rosacea will be recruited from the Wake Forest Baptist Health Dermatology Clinics and Institutional Review Board (IRB)-approved advertising. Subjects will be classified as having erythematotelangiectatic or a combination of erythematotelangiectatic and papulopustular. If they agree to participate, subjects will give written consent approved by the IRB and will be seen in follow up at months 3 and 6. The investigator is also interested in learning through the adherence surveys if subjects begin using the medication on an as needed basis, and if this affects the side effect profile and satisfaction with the medication.

Condition	Drug
Rosacea	Brimonidine topical gel 0.33%; internet survey
Sponsor: Wake Forest School of Medicine **Study ID Numbers:** 00036221 **ClinicalTrials.gov Identifier:** NCT02659670	

ACNE

Safety and Preliminary Efficacy of Combination Therapy for the Treatment of Acne Vulgaris

Acne vulgaris is a multifactorial, highly prevalent dermatologic condition that results in visible lesions that can be quite disfiguring. Consequently, individuals with acne often suffer from a wide range of psychological manifestations. Although there is consensus that combination therapy is most effective in treating acne, researchers are constantly striving to develop new treatment.

Microcurrent therapy (MCT) is a non-invasive modality that has successfully been used to promote wound healing and has been routinely used in aesthetics. Use of MCT alone or in combination with current successful treatment such as blue light phototherapy (BLP), may hold promise for acne treatment. The investigators propose to conduct a small randomized control trial to determine the safety and preliminary efficacy of a novel combination therapy to treat acne vulgaris. The investigators will recruit up to 60 males and females and randomly assign them to one of 3 arms: 1) BLP; 2) MCT; and 3) combination therapy (BLP and MCT). The investigators will assess physiological parameters (number of acne lesions, amount of sebum produced, degree of acne severity) and psychosocial factors (dermatologic quality of life, social anxiety, depressive symptomatology, self-esteem).

Participants will complete a baseline assessment prior to initiating treatment and a follow-up assessment at 4 weeks post termination of treatment. The investigators will conduct intermediary assessments at weeks 3 and 5, and 1 week post-termination of the treatment.

Condition	Intervention
Acne vulgaris	Blue light phototherapy; microcurrent therapy; combination of BLP and MCT
Sponsor: Nova Southeastern University **Study ID Numbers:** 08291420Exp **ClinicalTrials.gov Identifier:** NCT02431494	

Adapalene 0.3% - Benzoyl Peroxide 2.5% Gel and Risk of Formation of Atrophic Acne Scars

This is a multi-center, randomized, investigator blinded, vehicle controlled trial using intra-individual comparison (right half-face vs left half-face). Subjects will have each half-face randomized to one of the two following treatments: adapalene 0.3% - benzoyl peroxide (BPO) 2.5% gel (TactuPump® Forte) or vehicle gel.

The main objective of this trial is to evaluate the effect of adapalene 0.3% - BPO 2.5% gel vs vehicle gel on the risk of formation of atrophic acne scars in moderate to severe acne subjects. The estimated enrollment is 60 patients, with clinical diagnosis of moderate to severe acne vulgaris on the face defined by 1) an Investigator's Global Assessment score of 3 or 4, with the same score on both sides; 2) a minimum of 25 inflammatory lesions (papules and pustules) in total, with at least 10 on each side (excluding the nose); 3) no more than two acne nodules (≥ 1 cm); and 4) a minimum of 10 atrophic acne scars in total (upper than 2 mm) (excluding the nose).

Condition	Drug
Acne vulgaris; atrophic acne scars.	Adapalene 0.3% - benzoyl peroxide 2.5% gel
Sponsor: Galderma **Study ID Numbers:** RD.03.SPR.105061 **ClinicalTrials.gov Identifier:** NCT02735421	