Study of the Use of Low Level Laser Therapy to Reduce Acne

This study has been completed.

First Received on January 11, 2011. Last Updated on June 21, 2011 History of Changes

Sponsor:	**Erchonia** Corporation
Information provided by:	Erchonia Corporation
ClinicalTrials.gov Identifier:	NCT01276535

Purpose

The purpose of this study is to determine whether low level laser light therapy is effective in the treatment of acne blemishes.

Condition	Intervention
Acne	Device: **Erchonia** EML

Study Type: Interventional
Study Design: Endpoint Classification: Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Pilot Study to Evaluate the Efficacy of Low-level Laser Therapy in Reducing Blemishes by Quantifying a Decreasein Signs of Blemishes, Both Non-inflammatory and Inflammatory

Resource links provided by NLM:

MedlinePlus related topics: Acne

U.S. FDA Resources

Further study details as provided by Erchonia Corporation:

Primary Outcome Measures:

- Grade on the Burton et al. Acne Severity Grade scale [Time Frame: 6 weeks]
  [Designated as safety issue: No]

Secondary Outcome Measures:

- number of inflammatory lesions [Time Frame: 6 weeks] [Designated as safety issue: No]
- number of non-inflammatory lesions [Time Frame: 6 weeks]
  [Designated as safety issue: No]

Enrollment: 12
Study Start Date: March 2010
Study Completion Date: June 2010
Primary Completion Date: June 2010 (Final data collection date for primary outcome measure)

Intervention Details:

Device: **Erchonia** EML

The **Erchonia**® EML Laser is a dual-diode 7 mW laser of 635 nm and 405 nm wavelength. The light emitting diode is manufactured by Coherent and classified by the Center for Devices and Radiological Health (CDRH) as a Class IIIb laser diode. The EML is a hand-held device that uses rechargeable batteries or a separate AC power adapter.

Detailed Description:
Acne is a chronic inflammatory disorder plaguing the sebaceous follicle, and debate still remains over what truly initiates lesion formation. Experts agree that an increase in androgen production plays a significant role in the onset of acne. Androgens promote the increase in size of sebaceous glands and stimulate sebum production. The simple act of sebaceous gland stimulation via androgens could ultimately promote the upregulation of pro-inflammatory cytokines like TNF-α and IL-1α without propionibacteria even being present. The synthesis of IL-α and other pro-inflammatory cytokines including prostaglandins occurs via the inducible enzyme known as cyclooxygenase-2 (COX-2). Studies analyzing the pathogenesis of mucositis have identified COX-2 as an important contributor to the upregulation of pro-inflammatory cytokines and thus a major contributor to the progression of the disorder itself.

Recent evidence indicates that low-level laser therapy (LLLT) is able to significantly diminish the expression of COX-2, resulting in the reduction of inflammation. The ability to modulate the COX-2 pathways via LLLT is believed to inhibit the production of pro-inflammatory cytokines (i.e. TNF-α and IL- α) present in acne-prone skin.

Eligibility

Ages Eligible for Study: 18 Years to 40 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- signed informed consent form.
- male or female.
- 18 to 40 years.
- area sought for acne reduction is the face.
- diagnosis of moderate or severe acne vulgaris, defined as grade 3-5 according to the grading criteria of acne severity given by Burton et al.
- Acne has been ongoing for at least 3 months prior to screening and must include inflammatory lesions.
- female using hormonal birth control must have been on a stable dose for at least 3 months prior to screening.
- negative pregnancy test for female subjects, unless the female subject has been surgically sterilized.
- sexually active female subject who is not surgically sterile or 2 years post menopausal must

agree to use approved contraception/birth control measure while on study

- PI (A normal healthy patient) or P2 (A patient with mild systemic disease) on the American Society of Anesthesiologists (ASA) Physical Status Classification System.
- subject agrees to abstain from use of non-study treatments for acne while enrolled in the study.
- subject agrees to abstain from use of tanning beds/sunbathing while partaking in the study.
- subject agrees, and be able, to maintain regular medication schedule, as is medically feasible, during study participation.
- subject agrees to not change skin care regimen throughout study participation.
- subject is willing and able to comply with all requirements of the study protocol.

Exclusion Criteria:

- use of topical acne treatment within 15 days prior to start of study.
- use of oral acne treatment within 30 days prior to the start of study.
- use of oral isotretinoin or other systemic retinoids in the 12 months preceding the start of the study.
- use of systemic steroids within 30 days prior to the start of the study.
- pregnancy or currently nursing, or planning pregnancy during the course of the study
- participation in any clinical study involving an investigational product within 30 days of the start of the study
- use of tanning beds or sunbathing in the 30 days prior to the start of the study.
- history of keloids or other photosensitive disorders or use of any photosensitizing medication.
- currently taking any medication that may alleviate or exacerbate acne.
- Porphyria or known allergies to porphyrins.
- current signs or symptoms of severe, progressive, or uncontrolled renal, hepatic, hematologic, gastrointestinal, endocrine, pulmonary, cardiac, neurologic, or cerebral disease.
- known malignancy or history of malignancy other than non-melanoma skin cancer
- human immunodeficiency virus (HIV), hepatitis B or hepatitis C
- signs of bacterial, fungal or viral skin lesions that may interfere with assessment of acne vulgaris.
- known inherited or acquired coagulation defects.
- substance abuse (drug or alcohol) problem within the previous 3 years.
- developmental disability or cognitive impairment that may preclude study compliance.
- unlikely to comply with the study protocol and procedure administration protocol, or is considered unsuitable for participation in the study for any other reason in the opinion of the investigator.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01276535

Locations

United States, Texas

Westlake Dermatology
Austin, Texas, United States, 78746

Sponsors and Collaborators

Erchonia Corporation

More Information

No publications provided

Responsible Party:	Gregory A. Nikolaidis, MD, Westlake Dermatology
ClinicalTrials.gov Identifier:	NCT01276535 History of Changes
Other Study ID Numbers:	ECACNEP1
Study First Received:	January 11, 2011
Last Updated:	June 21, 2011
Health Authority:	United States: Institutional Review Board

Additional relevant MeSH terms:

- Acne Vulgaris
- Acneiform Eruptions
- Skin Diseases
- Facial Dermatoses
- Sebaceous Gland Diseases

ClinicalTrials.gov processed this record on September 05, 2012