# A Retrospective Analysis of the Effects of Low Level Laser Therapy on Toenail Onychomycosis



ClinicalTrials.gov Identifier: NCT02588599

Recruitment Status : Completed
First Posted : October 28, 2015
Results First Posted : July 21, 2016
Last Update Posted : September 28, 2016

**Sponsor:**
**Erchonia** Corporation

**Information provided by (Responsible Party):**
Erchonia Corporation

**Study Details** | **Tabular View** | **Study Results** | Disclaimer

How to Read a Study Record

## Study Description

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Brief Summary:

The purpose of this study is to determine whether low level laser therapy (LLLT) using the **Erchonia** LUNULA device is effective in increasing clear nail in toenails with onychomycosis.

| Condition or disease | Intervention/treatment | Phase |
|---|---|---|
| Onychomycosis | Device: **Erchonia** LUNULA | Not Applicable |

Detailed Description:

Nail onychomycosis, or fungus infection, is typically caused by a fungus called dermatophytes, but may also be caused by yeasts and molds. These microscopic organisms invade the skin through tiny invisible cuts or through a small separation between the nail and the nail bed. Under conditions of warmth and moisture, the fungi grow and spread. The infection begins as a white or yellow spot under the tip of the nail, and as it spreads deeper into the nail, causes unsightly and potentially painful nail discoloration, thickening and the development of crumbling edges. Onychomycosis occurs more commonly in toenails than in fingernails because toenails are often confined in a dark, warm, moist environment inside shoes where fungi can thrive. Toenail fungus affects approximately 23 million people in the US - about 10% of all adults.

Potential complications of onychomycosis include pain in the nails, permanent damage to the nails, development of other serious infections that can spread beyond the feet for individuals with a suppressed immune system due to medication, diabetes or other conditions, such as leukemia and AIDS.

Nail fungus can be difficult to treat, and repeated infections are common. Currently available treatments for onychomycosis include oral antifungal medications, antifungal lacquer, and topical medications, surgical nail removal and photodynamic therapy.

There is no perfect cure for toenail fungus. Even the most effective oral medications are successful only about half of the time, and topical medications are successful less than 10% of the time. Recently, research has found laser therapy to show promise as a novel alternative treatment for toenail onychomycosis. Unlike medication-driven treatments for toenail fungus which can have many side effects including serious ones such as liver toxicity, laser therapy presents minimal to no risk of side effects. Laser therapy is applied to toenail onychomycosis

by shining a laser light through the toenail into the tissue below. The laser light vaporizes the fungus while leaving the skin and surrounding healthy tissue unharmed.

Low level laser therapy operates under the principle of photochemistry with a photoacceptor molecule absorbing the emitted photons and inducing a biological cascade. Like our eukaryotic cell, fungi contain the highly complex organelle the mitochondria, which is responsible for the manufacturing of the energy molecule adenosine triphosphate (ATP). Within the inner mitochondrial membrane is cytochrome c oxidase, an identified photoacceptor molecule. It is believed that laser therapy could perhaps provide a means to photo-destroy the fungi responsible for onychomycosis (OM) by inducing the release of highly reactive superoxides. Moreover, laser therapy has been shown to promote superoxide dismutase (SOD), a process responsible for the destruction of foreign invaders. Extracellular release of low levels of mediators associated with SOD can increase the expression of chemokines, cytokines, and endothelial leukocyte adhesion molecules, amplifying the cascade that elicits the inflammatory response. The physiologic function of hydrogen peroxide, superoxide anion, and hydroxyl free radical is to destroy phagocytosed microbes. By enhancing the natural processes of the immune system and impacting the structural integrity of the fungi strain, it is believed that laser therapy may provide a means for clinicians to effectively treat OM without the onset of any adverse events.

## Study Design

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|---|---|
| Study Type : | Interventional (Clinical Trial) |
| Actual Enrollment : | 54 participants |
| Intervention Model: | Single Group Assignment |
| Masking: | None (Open Label) |
| Primary Purpose: | Treatment |
| Official Title: | A Retrospective Evaluation of the Effect of the **Erchonia** LUNULA™ on the Increase of Clear Nail in Patients With Toenail Onychomycosis |
| Study Start Date : | October 2015 |
| Actual Primary Completion Date : | October 2015 |
| Actual Study Completion Date : | October 2015 |

## Arms and Interventions

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| Arm | Intervention/treatment |
|---|---|
| Experimental: **Erchonia** LUNULA | Device: **Erchonia** LUNULA |

| Arm | Intervention/treatment |
| --- | --- |
| The **Erchonia** LUNULA emits both red light (635 nm) and blue light (405 nm) to the affected toenail for 12 minutes per treatment for 4 treatments, each treatment one week apart. | Active low level laser light therapy |

## Outcome Measures

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Primary Outcome Measures :

1. Percent (%) of Toenails Attaining 3 Millimeters (mm) or More of Clear Nail Growth [ Time Frame: 6 Months ]

   Individual toenail success criteria was defined as 3 millimeter (mm) or more of clear nail growth at 6 months post-procedure administration as evaluated relative to baseline. Overall study success criteria was defined as an 60% or more of treated toenails meeting the individual success criteria.

Secondary Outcome Measures :

1. Change in Millimeters (mm) of Clear Nail Bed [ Time Frame: Baseline and 6 Months ]

   Millimeter (mm) of clear nail from the base of the toenail was determined from digital photographs of the toenail using a computer program. Change in mm of clear nail bed was calculated as the difference in mm of clear nail bed from baseline measurement to the measurement at 6 months after the end of the procedure administration phase. An increase in mm of clear nail between the two measurement points indicates that the toenail has improved and is positive for study success. A decrease in mm of clear nail between the two measurement points indicates that the toenail has worsened and is negative for study success.

## Eligibility Criteria

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**Information from the National Library of Medicine** NIH NLM

*Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.*

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|---|---|
| Ages Eligible for Study: | 18 Years and older (Adult, Older Adult) |
| Sexes Eligible for Study: | All |
| Accepts Healthy Volunteers: | No |

**Criteria**

Inclusion Criteria:

- Great toenail presents with clearly visually identifiable and photographically documentable onychomycosis of the great toenail, or no visible onychomycosis (1 great toenail)
- Onychomycosis has been identified as due to bacterial/fungal infection classified by the investigator as onychomycosis, with the nail presenting positive on visual inspection for somewhat thickened nail plate with a cloudy appearance and some discoloration (white to yellow to brown)
- Onychomycosis etiology has been confirmed through positive fungal potassium hydroxide preparation (KOH) testing results

Exclusion Criteria:

- Spikes of disease extending to nail matrix in the great toenail
- Infection involving lunula of the great toenail, e.g. genetic nail disorders, primentary disorders
- Great toenail has less than 2mm clear (unaffected) nail plate length beyond the proximal fold
- Dermatophytoma or "yellow spike/streak" (defined as thick masses of fungal hyphae and necrotic keratin between the nail plate and nail bed) on the great toenail
- Onychogryphosis
- Proximal subungual onychomycosis
- White superficial onychomycosis

## Contacts and Locations

Go to

**Information from the National Library of Medicine** NIH NLM

*To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.*

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number):* ***NCT02588599***

**Sponsors and Collaborators**

**Erchonia** Corporation

**Investigators**

Principal Investigator: Kerry Zang, DPM

## More Information

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**Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):**

Zang K, Sullivan R, Shanks S. A Retrospective Study of Non-thermal Laser Therapy for the Treatment of Toenail Onychomycosis. J Clin Aesthet Dermatol. 2017 May;10(5):24-30. Epub 2017 May 1.

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|---|---|
| Responsible Party: | Erchonia Corporation |
| ClinicalTrials.gov Identifier: | NCT02588599 History of Changes |
| Other Study ID Numbers: | EC_LUNULA_RETRO |
| First Posted: | October 28, 2015 Key Record Dates |
| Results First Posted: | July 21, 2016 |
| Last Update Posted: | September 28, 2016 |
| Last Verified: | August 2016 |

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Additional relevant MeSH terms:

- Onychomycosis
- Tinea
- Dermatomycosis
- Skin Diseases, Infectious
- Infection
- Mycoses
- Nail Diseases
- Skin Diseases