

Trial Study to Evaluate Oral Terbinafine Treatment in Conjunction with Laser Therapy

Patients are excluded if:

1. They have existing conditions not allowing them to take oral medication including liver disease, drugs that may interact with terbinafine, or have experienced an allergic reaction with the use of terbinafine.
2. Patients having systemic diseases that may cause nail disease such as Psoriasis, Lichen Planus, and Eczema
3. Patients with a history of traumatic injury which can be related to abnormal nail growth.
4. Patients cannot have taken any oral medication for the treatment of nail fungus within 2 years prior to starting the study.
5. Patients cannot have had a laser treatment within the past 6 months or had clearing of the nails.
6. Patients with immunosuppressive medications such as corticosteroids, chemotherapy medications, or methotrexate maybe excluded from the study.

Treatment Protocol

1. 4 Laser Treatments at Day 1 at one month intervals.
2. Parameters for the Genesis Plus are:
 - a. Fluence 18J/cm²
 - b. Pulse Width 0.3ms
 - c. Frequency 3hz
 - d. Spot Size 5mm
 - e. 1064nm nd:yag Genesis Plus Laser System
3. Oral medication will be administered in pulse dose regimen with the first of each laser treatment, the first pill to be taken 2-3 hours prior to the laser treatment.
4. Nails will be debrided as needed to a level where there is no more than 2mm in thickness anywhere along the nail plate.
5. Terbinafine Cream 1% is to be applied on day 1 of the treatment 2 times a day for 3 weeks along the bottom of both feet and between all of the toes.
6. SteriShoe must be used in shoes prior to wearing them each day for the first 3 weeks while the topical terbinafine cream is being applied.

Cost of Study and others receiving this Treatment Protocol

1. People not having previously been treated at totally feet and individuals not accepted into the study will be charged our special price of \$880
2. People that are accepted into the study and have had a laser treatment at Totally Feet Podiatry and Laser Center will pay \$440

What is Included in the Study

1. 4 Laser Treatments spaced at 1 month intervals.
2. 28 250mg tablets of terbinafine
3. 1 Tube of 1% terbinafine Cream
4. Detailed instructions for the study and what is expected of the patients participating in the study parameters.
5. FU 6 months
6. FU 12 months
7. FU 18 months

Theory: Laser Treatment and Timed Oral Terbinafine = Increased Efficacy

The premise for the study revolves around the synergistic effects of the laser and oral terbinafine 250mg tablets taken with pulse dosing. The laser energy should increase the exposure of the tissues infected to terbinafine. This will occur via two mechanisms:

1. Direct heating of the areas treated with the laser will cause vasodilation increasing the areas exposure to the medication
2. The laser energy causes collagen reorganization, this process will increase the vascular flow to the area. This increased vascular flow will increase the concentration of the terbinafine in the laser treated areas.

The increased exposure to terbinafine and the destructive nature of the 1064nm nd:yag laser will work synergistically to improve the rates of mycological cure and improve the appearance of the nails.