

REGRAS DE SUBMISSÃO - TRABALHO EXPERIMENTAL / EXPERIMENTAL
WORK

**LOW INTENSITY LASER ON VENOUS ULCER HEALING: RANDOMIZED
CLINICAL TRIAL**

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OBJECTIVE

To evaluate the effectiveness of Low Intensity Laser Therapy associated with the use of Unna boots in relation to the size and bed of the lesion, exudation, odor, edema and algia in people with venous ulcers.

METHODS

Triple-blind, longitudinal and prospective Randomized Clinical Trial (RCT) approved by the Human Research Ethics Committee under CAAE: 67137323.8.0000.0121, opinion no. 5.972.232, and entered in the Brazilian Registry of Clinical Trials (ReBEC), under protocol RBR-59fb8f6. The sample was intentional, non-probabilistic, with a 5% significance level and 95%

confidence interval. Of the 38 participants, six were excluded in accordance with the eligibility criteria, resulting in 32 patients. Inclusion criteria were: being over 18 years old, having a medical diagnosis of venous ulcer, with vascular Doppler, or an Ankle Brachial Index (ABI) between 0.6 and 1.2, being treated with inelastic compressive therapy, and being available to attend the health service or be seen at home at least once a week. Those who agreed to take part signed a Free and Informed Consent Form (FICF) and a photo authorization form. Data collection took place from September 2023 to July 2024. Participants were allocated to either the Control Group (CG) or the Experimental Group (EG) by means of simple randomization, with a 1:1 ratio between the groups, carried out via the website: randomized.org. Follow-up lasted 90 days and took place over twelve sessions: D1 (when the patient was included); D2 (seven days after D1); D3 (15 days after D1); and so on, with weekly follow-ups. Data was collected using the following instruments: the PUSH scale, Visual Analog Scale (VAS), GODET and TELLER scales once a month. Each month, on the first and last day of follow-up, the clinical characteristics of the wound were checked, consisting of the area (measured with a millimeter ruler), bed, edge, exudate and odor. Finally, the wound was photographed using a camera built into a cell phone with a triple camera, with 12, 12 and 8 megapixels respectively, without flash, and a resolution of 4000 x 3000 pixels. Data analysis was descriptive in relation to categorical variables presented as absolute and percentage frequencies, statistical tests using Generalized Estimation Equations and Fisher's exact test.

RESULTS

In terms of socio-demographic and clinical characteristics, there was no statistically significant difference between the two groups investigated. After 90 days in the experimental group there was greater efficacy in relation to edema ($p=0.001$), pain (0.007), size ($p=0.016$), exudate ($p=0.031$), tissue bed ($p=0.007$) and healing ($p\text{-value}=0.016$).

CONCLUSION

The application of laser therapy as an adjuvant associated with Unna boot compressive therapy was effective in the venous ulcer healing process.

Palavras-chave: keywords: varicose ulcer low-intensity light therapy randomized clinical trial.