PROTOCOLOS DE INVESTIGACIÓN - MEDICINA

EFFECT OF PHOTOBIOMODULATION ON THE HEALING OF VENOUS ULCERS IN THE LOWER LIMBS: A DOUBLE-BLIND RANDOMIZED CONTROLLED CLINICAL STUDY

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Venous ulcers (VUs) are a major public health issue due to their chronic nature, high recurrence, and significant impact on patients' quality of life, as well as economic and social burdens. The standard treatment includes topical agents,

pharmacotherapy, and compression therapy. Photobiomodulation (PBM) has shown promise in enhancing wound healing and improving patient outcomes. This randomized, controlled, double-blind clinical trial aims to evaluate the efficacy of PBM combined with compression therapy (gold standard) in accelerating the healing of VUs in the lower limbs.A total of 104 participants will be randomly assigned to two groups: the Experimental Group (n=52), receiving PBM (6 J per emitter, 4 red light emitters at 660 nm and 4 infrared emitters at 808 nm, total power 800 mW) combined with compression therapy; and the Control Group (n=52), receiving compression therapy and sham PBM. Treatments will occur twice weekly over 16 weeks (32 sessions total), following routine care at the Lençóis Paulista Health Unit. PBM or sham PBM will be applied by a trained nurse, while outcomes will be assessed weekly by a blinded researcher.The primary outcome of the study will be wound healing, measured by the percentage reduction rate in wound volume over the 16-week treatment period. Secondary outcomes will include changes in wound dimensions, healing rate, adverse effects, wound quality (Bates-Jensen Scale), pain (VAS), quality of life (SF-36), wound temperature (infrared thermography), clinical severity (VCSS), and treatment costs. Wound size will be objectively measured using the Imitowound® app with smartphone images. Data will be analyzed using appropriate statistical tests, including ANOVA or Kruskal-Wallis, chi-square or Fisher's exact tests, and Kaplan-Meier survival analysis with log-rank testing, considering $p < 0.05$ as significant. Positive findings may support PBM as a valuable adjunct in VU treatment.

Palavras-chave: photobiomodulation; venous ulcers; varicose ulcers.