

PROTOCOLOS DE INVESTIGACIÓN - ENFERMERÍA

EFFECTS OF TRANSCUTANEOUS VASCULAR LASER IRRADIATION ON VENOUS ULCERS: A RANDOMIZED CONTROLLED TRIAL PROTOCOL

Rosângela A Oliveira (rosangela.o@uni9.edu.br)

Rebeca Boltes (rebeca.boltes@uni9.pro.br)

Introduction: Intravascular Laser Irradiation of Blood (ILIB), recently termed Vascular Photobiomodulation (VPBM), is a therapeutic technique that uses low-intensity laser irradiation to modulate oxidative stress, reduce inflammation, and improve microcirculation. VPBM has shown promise in treating different chronic wounds, such as diabetic foot or venous ulcers, which exhibit local and systemic alterations characterized by elevated oxidative stress and persistent inflammation. Peripheral blood microscopy (dark-field and bright-field, DFM) and thermography provide tools to analyze VPBM's effects in these contexts. Objective: to investigate VPBM's effects on systemic and local tissue in patients with venous ulcers by evaluating morphological changes in peripheral blood (DFM) and thermal patterns (thermography) and correlate inflammatory/oxidative markers (IL-6, IL-1 β , TNF- α , C-Reactive Protein CRP) with clinical progression and tissue regeneration. Methods: A prospective, randomized, controlled trial (SPIRIT-compliant) will be conducted after ethics committee approval. Twenty participants with unilateral right leg venous ulcers

will be enrolled according to the following criteria: patients with chronic venous ulcers lasting more than six months, with unilateral right leg venous ulcers and aged between 18 and 70 years. Patients with hematological diseases and severe systemic infections will be excluded. All participants will be randomized into: Intervention group (standard care + transcutaneous VPBM application over the radial artery, 660 nm, 100 mW, 60 minutes/session, 360 J/session, twice weekly for 4 weeks) and control group (standard care alone). Peripheral blood markers (IL-6, IL-1 β , TNF- α , CRP), DFM, and thermographic imaging will be performed at baseline (Day 1) and Days 7, 14, and 21. Epidemiological data will be collected from medical records. Adverse effects will be monitored. Data normality will be assessed using the Kolmogorov-Smirnov test. Parametric or non-parametric tests will compare pre- and post-intervention outcomes within and between groups (SPSS IBM; *p* < 0.05). Anonymized data will be analyzed.

Palavras-chave: intravascular laser irradiation of blood (ilib); peripheral blood microscopy; vascular photobiomodulation (vpbm); leg venous ulcer.