

## PROTOCOLOS DE INVESTIGACIÓN - FISIOTERAPIA

### **PREVENTION OF EARLY-STAGE PRESSURE INJURIES IN HIGH-RISK PATIENTS USING PHOTOBIMODULATION: A RANDOMIZED CONTROLLED CLINICAL TRIAL**

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Pressure injuries (PIs) are frequent adverse events in hospitalized patients, ranking among the top causes of harm. Photobiomodulation (PBM) has shown benefits in wound healing, inflammation reduction, and tissue regeneration. While its use in advanced PIs is documented, application in early stages (Stages 1 and 2) is less explored. This study hypothesizes that early PBM intervention can prevent PI progression, reduce complications, and improve quality of life. This randomized controlled clinical trial will include 200 high-risk patients

(Braden Scale < 9) with Stage 1 or 2 PIs. Participants will be randomly assigned to a PBM Group (n = 100), receiving irradiation in at-risk areas five times per week, or a Control Group (n = 100), receiving simulated PBM. Both groups will receive standard care, including wound cleansing, debridement, and dressings. The primary outcome is PI progression to more advanced stages. Secondary outcomes include time to PI development or regression, local pain intensity (Visual Analog Scale – VAS), wound healing score (PUSH scale), health-related quality of life (EQ-5D), number of dressing changes, adverse events, and patient satisfaction. Assessments will occur at baseline, week 1, and week 2 post-intervention. Data will be analyzed at a 5% significance level ( $p < 0.05$ ) using an intention-to-treat approach. PI progression will be compared between groups with Fisher's exact or chi-square test. Continuous variables (VAS, PUSH, EQ-5D) will be tested for normality (Shapiro-Wilk) and compared with Student's t-test or Mann-Whitney test. Intraindividual changes will be assessed with repeated measures ANOVA or Friedman test, according to data distribution.

Palavras-chave: photobiomodulation; pressure injury prevention; wound healing.