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Randomized Controlled Trial

> [Lasers Med Sci](#), 31 (4), 811-6 May 2016

# A Randomized Pilot Study to Assess the Safety and the Value of Low-Level Laser Therapy Versus Clonazepam in Patients With Burning Mouth Syndrome

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PMID: 26873501 DOI: [10.1007/s10103-016-1897-8](https://doi.org/10.1007/s10103-016-1897-8)

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## Abstract

Comparison between low-level laser therapy (LLLT) and clonazepam for treating burning mouth syndrome (BMS) patients has never been documented; the aim of this study was to assess the effects of LLLT photobiomodulation versus medical therapy with clonazepam on BMS. Thirty-three patients (25 female, 8 male, mean age = 67.12) were randomly allocated to two different groups: the first one (group A, 18 patients) underwent two laser irradiation sessions weekly for 5 weeks, whereas the second one (group B, 15 patients) received topical clonazepam therapy [half a tablet (2 mg) in the mouth without swallowing for 3 min, three times a day for 21 days]. LLLT was delivered with a continuous wave 980-nm aluminum gallium arsenide (AlGaAs) diode laser and the output of 300 mW, delivering a Fluence of 10 J/cm(2), using a "spot technique," with an average power density of about 1 W/cm(2). The laser probe was held perpendicularly at a distance of about 2 mm from the mucosa. Visual analogue scale (VAS), McGill Pain Questionnaire, present pain intensity (PPI), and Oral Health Impact Profile (OHIP-49) assessed sensation of pain. Hospital Anxiety and Depression Scale and Geriatric Depression Scale assessed levels of anxiety and depression. Twelve weeks after the end of treatment, patients treated with LLLT experienced a decrease in pain sensation reported for all the parameters analyzed: VAS (P = 0.004), McGill Pain Questionnaire (P = 0.002), PPI (P = 0.002), and OHIP-49 (P = 0.010). The group treated with clonazepam had less favorable results for VAS (P = 0.33), McGill Pain Questionnaire (P = 0.005), PPI (P = 0.013), and OHIP-49 (P = 0.25). Levels of anxiety and depression did not change

statistically in any groups ( $P > 0.05$ ). Comparing the two groups, LLLT appeared to be superior in improving pain perception, but statistically only at 8 weeks after the end of the protocol proposed ( $P = 0.026$ ). Based on this preliminary trial, LLLT is capable of reducing the symptoms of patients with BMS with a constant and long-lasting effect, experienced since the end of the first applications.

**Keywords:** BMS; Clonazepam; Low-level laser therapy; Randomized.

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