Effects of a new mixed laser wavelength 10600 + 1540 nm on the genitourinary syndrome in postmenopausal women: a single-blind randomized parallel controlled trial

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Abstract

Objectives. To evaluate the efficacy and safety of a mixed wavelength laser 10600 and 1540 nm using low-power 5 W CO2, on the vaginal maturation value (VMV) and genitourinary syndrome of menopause (GSM). Design. randomized single-blind sham-controlled trial. Setting. Hospital Universitari Sant Joan de Reus, Spain. Population. 31 postmenopausal women with GSM symptoms and VMV <50%. Methods. Patients were randomized to laser or sham intervention, consisting of monthly laser or sham treatments for three consecutive months. Evaluations were at baseline, 3- and 9-months post-intervention. Main outcome measures. The primary outcome was the effect on VMV; secondary outcomes were vaginal pH, and visual analogue scale (VAS) for GSM symptoms at 3 and 9 months. Also, adverse events were evaluated. Results: 27 patients completed the study, 14 were randomly assigned to the laser arm and 13 to the sham arm. At 3 months, VMV increased significantly in the laser group (44.5% ± 4.4) compared to sham group (27.7% ± 6.3) (P = 0.033), at 9 months, VMV in the laser group was similar to baseline values and VAS scores for GSM decreased for dyspareunia in the laser group compared to the sham group (P = 0.049). Vaginal pH remained unchanged. Treatment was well tolerated with adverse effects equivalent to the sham group. Conclusions: At the first 3 months, mixed laser wavelengths 10600 + 1540 nm increased VMV and at 9 months, dyspareunia was reduced. Laser treatment was safe and well tolerated with adverse effects similar to the sham group. ClinicalTrialRegistry NCT039565

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`Table 1. Baseline Characteristics of Participants.docx` available at https://authorea.com/users/564933/articles/611954-effects-of-a-new-mixed-laser-wavelength-10600-1540-nm-on-the-genitourinary-syndrome-in-postmenopausal-women-a-single-blind-randomized-parallel-controlled-trial

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`Table 2. VMV. docx.docx` available at https://authorea.com/users/564933/articles/611954-effects-of-a-new-mixed-laser-wavelength-10600-1540-nm-on-the-genitourinary-syndrome-in-postmenopausal-women-a-single-blind-randomized-parallel-controlled-trial

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Table 3 VAS for GSM.docx available at https://authorea.com/users/564933/articles/611954-effects-of-a-new-mixed-laser-wavelength-10600-1540-nm-on-the-genitourinary-syndrome-in-postmenopausal-women-a-single-blind-randomized-parallel-controlled-trial

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Table 4.PGI.docx available at https://authorea.com/users/564933/articles/611954-effects-of-a-new-mixed-laser-wavelength-10600-1540-nm-on-the-genitourinary-syndrome-in-postmenopausal-women-a-single-blind-randomized-parallel-controlled-trial

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Table 5. COMPLICATIONS.docx available at https://authorea.com/users/564933/articles/611954-effects-of-a-new-mixed-laser-wavelength-10600-1540-nm-on-the-genitourinary-syndrome-in-postmenopausal-women-a-single-blind-randomized-parallel-controlled-trial

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Figure 1. CONSORT FLOW DIAGRAM.docx available at https://authorea.com/users/564933/articles/611954-effects-of-a-new-mixed-laser-wavelength-10600-1540-nm-on-the-genitourinary-syndrome-in-postmenopausal-women-a-single-blind-randomized-parallel-controlled-trial