

A Novel, Non-Invasive Microwave-Based Device for the Treatment of Axillary Hyperhidrosis

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Purpose: A new non-invasive microwave device was developed to treat axillary hyperhidrosis. This study reports a large, multicenter, randomized, sham-controlled clinical trial investigating efficacy and safety.

Methods: 120 adult subjects were randomized to treatment group (n=81) or sham group (n=39) and were treated in two sessions spaced two weeks apart. Each axilla was marked using a template, anesthetized using local anesthesia, and treated using a device handpiece that delivers microwave energy through the skin. Follow-up was 6 months for the sham group and 12 months for the treatment group.

Results: The mean age of subjects was 32.8 years; 58% of the subjects were female.

The primary efficacy measure was the percentage that had HDSS scores reduced to 1 or 2 (from 3 or 4 at baseline), implying sweat that was not noticeable or was tolerable. Results for the treatment group were 89% at 30-days post-treatment, 67% at 6-months, and 69% at 12-months. Sham group results were 54% at 30-days and 44% at 6-months ($p < 0.001$ at 30 days and $p = 0.019$ at 6 months). Additionally, 91% of treated subjects showed at least a one point decrease in HDSS score at 30 days, and 81% at 12-months.

Treatment-related adverse events were generally mild and all but one completely resolved. The most common adverse events were transient patches of altered sensation in the skin of the treated arm (n=9, 9.9%). Most subjects experienced transient post-treatment local sequelae in the axilla including edema, tenderness, and bruising.

Conclusion: A new microwave-based device and procedure has been developed with a very high efficacy for treating axillary hyperhidrosis, with results that show promising stability for long-term relief.

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