

A randomized, controlled trial to assess the efficacy and safety of a transdermal delivery system of nicotine/mecamylamine in cigarette smokers

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ABSTRACT

Aims To determine the efficacy and safety of nicotine transdermal therapy co-administered with the nicotine antagonist, mecamylamine, compared to a nicotine transdermal patch alone (21 mg nicotine + 6 mg mecamylamine, 21 mg nicotine + 3 mg mecamylamine, and 21 mg nicotine + 0 mg mecamylamine). **Design** Multi-center ($n = 4$), double-blind, randomized, parallel group, repeat-dose study. **Setting** Clinical laboratory. **Participants** A total of 540 subjects were enrolled into the study—135 from each of four sites; 180 patients in each of three treatment arms. **Intervention** Treatment was administered for the first 6 weeks of the 8-week study. Patients were instructed to continue smoking for the first 2 weeks of treatment. **Measurements** The primary efficacy parameter was 4-week continuous abstinence after the quit date, confirmed with an expired carbon monoxide of < 10 parts per million. **Findings** Analysis of the 4-week continuous abstinence for the intent-to-treat population showed overall rates of 29% (nicotine + 6 mg mecamylamine), 29% (nicotine + 3 mg mecamylamine) and 23% (nicotine only) using the slip definition which allows smoking in the first 2 weeks after the quit date. Statistical analyses revealed no significant treatment differences. Analyses using the strict definition (no smoking after the quit date) yielded similar non-significant group differences (29%, 27%, 26%). **Conclusion** If adding mecamylamine to nicotine replacement therapy (NRT) improves the chances of success at stopping smoking, the results of this study suggest that the effect is very small.

Keywords Clinical trial, mecamylamine, nicotine replacement, smoking cessation, transdermal patch.

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