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Title: A randomised placebo controlled trial to evaluate the effects of butamirate and dextromethorphan on capsaicin induced cough in healthy volunteers

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Body: Introduction: Butamirate (Sinecod) preparations and dextromethorphan are widely used OTC medications for cough. Here we evaluate the anti-tussive efficacy of butamirate and dextromethorphan on capsaicin-induced cough in healthy volunteers. Methods: This was a randomized, placebo-controlled, investigator-blind, 6-way cross-over study. The effect of dextromethorphan 30mg (20mls syrup), 4 doses of butamirate (22.5,45,67.5 and 90mg corresponding to 15,30,35 and 60mls of syrup) and placebo (matched for butamirate 30mls) was evaluated on incremental capsaicin challenge. The cough challenges were performed at baseline and 2,4,6,8,12 and 24 hours following dosing. The primary endpoint was the Area Under the Curve of log₁₀ C5 resulting from pre-dose to 12 hour post-dose. The association of plasma butamirate metabolite measurements and cough sensitivity parameters was analysed to establish pharmacokinetic and pharmacodynamic relationships. Results: Data from 34 subjects (13 males, median age 26 years) was analysed. All arms of the study including placebo were associated with a decrease in cough reflex sensitivity. Dextromethorphan was superior to placebo (p=0.01) and whilst butamirate's effect failed to reach significance, the maximum attenuation was observed with the 45 mg dose. No apparent relationship between pharmacokinetic and pharmacodynamic parameters for butamirate was observed at any time points. Conclusions: We have demonstrated for the first time that dextromethorphan attenuates capsaicin induced cough. The failure of Butamirate to demonstrate significant attenuation was possibly because of formulation issues at higher doses.