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Title

Association between substance use and acute rhinosinusitis in a multisite trial pilot study

Priority 1 (Research Category)

Clinical trial

Presenters

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Abstract

Context: Substance use may contribute to sinusitis frequency and severity by weakening the immune system or irritating and damaging nasal tissue. A pilot trial of the NOSES study was conducted to assess the feasibility for a full-scale trial. Objective: To evaluate the association between substance use and duration of acute sinusitis symptoms. Study Design and Analysis: Our study is a secondary outcome analysis of a pilot 4-arm randomized controlled trial. Participants were enrolled at 1-21 days of illness and followed via daily symptom survey. At day 9 post symptom onset (PSO), participants were assessed via study team phone call, and if they were still experiencing symptoms went forward with randomization to receive study drugs or placebo. Patients were administered the Tobacco, Alcohol, Prescription Drugs and Substance Use (TAPS)-1 survey to query about substance use on initial enrollment. Setting or Dataset: Participants were enrolled from primary care settings including outpatient clinics and urgent care from 6 practice-based research networks distributed across the United States. Population Studied: Adults with symptoms of acute rhinosinusitis.

Intervention/Instrument: Intervention was amoxicillin vs placebo, with or without budesonide. Outcome Measures: Sinus conditions were assessed via the mSNOT survey. Substance use was assessed with TAPS-1. Results: Of the 140 participants enrolled, 53 did not have worsening symptoms at day 9 PSO and

did not receive a study drug or placebo (NR) while 87 went forward with randomization (RAN). In the NR group, 7.8% attested to smoking tobacco daily/weekly while 16.1% of the RAN group responded that they smoked daily/weekly. Alcohol use was similar between the NR and RAN groups, with 11.8% and 6.9% reporting daily/weekly use and 31.4% and 33.3% reporting monthly use respectively. For illicit drug use, in the RAN group 7.0% reported daily/weekly use and 13.9% reported monthly use; while 11.5% of the NR group reported daily/weekly use and 15.4% reported monthly use. Additional data will be presented on the substance use and illness trajectories of the pilot study. Conclusions: Data from the pilot study shows that the RAN group had a higher proportion of daily smokers. Alcohol, prescription drug and illicit drug use did not show any strong association between the NR and RAD. The larger, full-scale trial will provide more data on the association between acute rhinosinusitis and substance use.

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