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Title

Adjunctive Saline Nasal Irrigation for Acute Rhinosinusitis: Results of a Randomized Pilot Study

Priority 1 (Research Category)

Clinical trial

Presenters

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Abstract

CONTEXT Acute rhinosinusitis (ARS) affects 15% of the adult population annually, and accounts for 20% of adult outpatient antibiotic prescriptions. Evidence is needed to clarify effectiveness of standard treatment, which includes antibiotics and intra-nasal corticosteroids (INCS), and supportive care including saline nasal irrigation (SNI), which is reported safe and effective for limiting sino-nasal symptoms but is poorly studied in ARS. OBJECTIVE We assessed feasibility and patient-reported clinical outcomes of adjunctive use of SNI in ARS. STUDY DESIGN/INTERVENTION The PCORI-funded NOSES (Nasal Steroids, Nasal Irrigation, Oral Antibiotics and Subgroup Targeting for Effective Management of Sinusitis) study has completed a double-blind, 4-arm (antibiotics vs antibiotics+INCS vs INCS vs placebo antibiotics) feasibility RCT. Participants in six U.S. practice based research networks were followed in pre-randomized (days 0-9) and randomized (days 10-23) phases. INTERVENTION All participants were provided with SNI materials (neti pot, salt packets, and distilled water) and advised to use twice daily as part of supportive care. SETTING/POPULATION/OUTCOME MEASURES Outpatient, participants with ARS. Primary: days participants used SNI at least once assessed in daily diary. Secondary: average rate of SNI use, percentage of participants who used SNI at least 50% of study days; perceived effect on sino-nasal symptoms; association of SNI use with validated clinical outcomes instrument severity score. RESULTS:

140 participants in both phases of the study completed 1606 of 1727 possible diary entries (93%); 534 diary entries noted SNI use (33%). Pre-randomized participants reported using SNI 37.6% (SD=34.0) of the time independent of days in the study. Randomized participants used SNI 36.8% (SD=38.4) of days in the study. Among pre-randomized participants (n=110), 51 (46%) participants reported using SNI on a least 50% of study days; among randomized participants (n=87), 27 (31%) did so. SNI use varied by study site (P<.0001). 330 (81%) of diary entries noting SNI use reported it reduced nasal/sinus symptoms. SNI use and self-reported clinical outcomes scores were not associated in either study phase.
CONCLUSIONS: Participants in this pilot study used SNI in both pre-randomized and randomized phases of the of the study, though adherence was low. Results suggest the need to enhance SNI adherence strategies.