NAPCRG 52nd Annual Meeting — Abstracts of Completed Research 2024.

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Title

NOSES (Nasal Steroids, Nasal Irrigation, Oral Antibiotics and Subgroup Targeting for Effective Management of Sinusitis) Trial

Priority 1 (Research Category)

Acute respiratory infections

Presenters

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Abstract

Context: Acute rhinosinusitis (ARS) is so prevalent that it affects 15% of the adult population annually, and accounts for 20% of all antibiotics prescribed to adults in the outpatient setting. Evidence is needed to demonstrate the most effective treatment, but many question whether patients would enroll in a trial if they might be randomized to no antibiotics. Objective: To compare, through patient-reported outcomes, the efficacy of oral antibiotics (amoxicillin-clavulanate) and intranasal corticosteroids (INCS) for clinical improvement of ARS among patients who do not improve with supportive care alone. Study Design: The NOSES (Nasal Steroids, Nasal Irrigation, Oral Antibiotics and Subgroup Targeting for Effective Management of Sinusitis) trial is funded by PCORI. We have completed the feasibility phase to demonstrate recruitment feasibility. It is a double blinded 4-arm (antibiotics vs antibiotics+INCS vs INCS vs placebo antibiotics) randomized controlled trial. Setting & Population Studied: Six primary care practice-based research networks (PBRNs) recruited adult patients with ARS. Instrument: The primary outcome is a disease-specific quality of life score, the patient-oriented mSNOT-16 which has been validated for primary care patients with ARS. The full study is powered for multiple aims, but this presentation is reporting on the overall success of the pilot. The primary goal of the pilot study was to demonstrate we could recruit for a placebo-controlled trial, receive feedback from key collaborators,

work with a patient advisory committee and overall learn important lessons for a full study, which will require recruiting over 3,700 ARS patients. Before patients are randomized they need to have 10 days of symptoms, thus we also assessed supportive care, with particular attention on nasal irrigation. Results: In 2 months the sites enrolled 140 participants. 87 of the participants' symptoms progressed and were randomized. Of the remaining 53 participants, over 90% improved before day 10. Conclusions: It is feasible to recruit and retain participants for an ARS study, randomizing participants to options that include no antibiotics. The success of the feasibility phase demonstrates the ability of the six PBRNS to recruit 3700 patients for this critical ARS trial. Lessons learned will inform refinements to the study protocol. Similar feasibility phases may be useful before launching other large national clinical trials