

Nasal Steroids, Irrigation, Oral Antibiotics, and Subgroup Targeting for Effective Management of Sinusitis

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. 18-75 years old; AND are experiencing either: 2. "persistent" symptoms or signs compatible with ARS or sinus infection lasting for 1-21 days without any evidence of clinical improvement (Symptoms include facial pain or pressure, facial congestion or fullness, nasal obstruction, nasal discharge, no or reduced sense of smell, fever $\leq 39^{\circ}\text{C}$ or 102°F , headache, bad smelling breath, fatigue, ear pain or pressure, and dental pain); OR 3. onset with worsening symptoms or signs characterized by the new onset of fever, headache, or increase in nasal discharge following a typical viral upper respiratory infection (URI) that lasted 5-6 days and were initially improving ("double-sickening").

Exclusion Criteria:

* allergy or intolerance to penicillin * received systemic antibiotic therapy in the past 4 weeks * prior sinus surgery (cosmetic surgery, such as rhinoplasty, septal deviation, etc. are not exclusionary) * complications of sinusitis (facial edema (swelling), cellulitis), or orbital, meningeal or cerebral signs) * health care clinician determined IV (intravenous) antibiotics or hospital admission are required * pregnancy or breastfeeding * presence of a comorbidity or medication that may impair a patient's immune response as determined by a health care clinician * hospitalization in past 5 days * unable or unwilling to provide informed consent or comply with study protocol requirements * fever $\geq 39^{\circ}\text{C}$ or 102°F today * taking intranasal corticosteroids (INCS) regularly in the past two weeks and unwilling to stop its use while in the study; OR * previously enrolled or participated in the feasibility phase or this stage of study

Conditions & Interventions

Interventions:

DRUG: Amoxicillin/Clavulanate Potassium 875 MG-125 MG Oral Tablet, DRUG: Placebo, DRUG: Budesonide nasal spray, OTHER: C-reactive protein

Conditions:

Sinus Infection, Acute Sinusitis

Keywords:

sinusitis, antibiotics, intranasal corticosteroids, saline nasal irrigation, comparative effectiveness

More Information

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Principal Investigator:

Phase: PHASE4

IRB

Number:

System ID: NCT06076304

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