Comparative Effectiveness of Available Treatments for Sinus and Ear Infections in Children (Acute Sinusitis)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 2 years to 12 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Age 2 years to <12 years.
- Clinical diagnosis of AS.

Exclusion Criteria:

- Known allergy or other contraindication to oral amoxicillin or clavulanate
- Prior use of systemic antibiotics in the last 7 days
- History of renal impairment
- History of hepatic impairment
- Phenylketonuria or allergy to aspartame
- History of craniofacial abnormalities
- Concurrent bacterial infection requiring systemic antibiotic therapy (e.g., pneumonia, streptococcal pharyngitis)
- Ill appearance, systemic toxicity, or immunodeficiency
- Incomplete pneumococcal vaccination, defined as receipt of fewer than three doses of a pneumococcal conjugate vaccine
- Parent or caregiver unable to complete study surveys in English or Spanish
- Previous randomization into either MEASURE trial within the last 6 months
- Periorbital redness and/or swelling, proptosis, or swelling of the forehead
- Individuals who qualify for both the AS and AOM trials (to avoid dual enrollment) will be excluded from the AS trial.

Conditions & Interventions

Interventions:
DRUG: Amoxicillin, DRUG: Amoxi Clavulanate, DRUG: Amoxicillin Placebo, DRUG: Amoxicillin-Clavulanate Placebo
Conditions:
ACUTE SINUSITIS, Sinusitis
Keywords:
Pediatric Sinusitis, Sinusitis

More Information

Description:
This study is being conducted at multiple hospitals and clinics to better understand whether antibiotics truly help children feel better when they have a sinus infection (acute sinusitis). Children in the study are randomly assigned (like flipping a coin) to receive either amoxicillin, amoxicillin-clavulanate, or a placebo (a look-alike medicine with no active antibiotic). Neither families nor study staff know which treatment the child is receiving during the study. The main goal is to compare how severe children's symptoms are each day while on these treatments. Parents or caregivers will report symptoms daily using a simple electronic diary. The study will also examine whether factors such as the severity of the child's illness or signs of allergies affect how well antibiotics work. The results will help guide better treatment decisions for children with sinus infections.

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