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

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 6 months to 36 months old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria

- Age 6 months to <36 months.
- Clinical diagnosis of AOM.

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
- Mastoiditis
- Conjunctivitis
- Temperature ≥39°C and AOM-SOS score ≥35
- Cochlear implants
- Spontaneous tympanic membrane perforation with otorrhea at presentation (participants who develop perforation and otorrhea after consent remain eligible)

Conditions & Interventions

Interventions:
DRUG: Amoxicillin, DRUG: Amoxicillin-Clavulanate, DRUG: Amoxicillin Placebo, DRUG: Amoxicillin-Clavulanate Placebo
Conditions:
Acute Otitis Media (AOM)
Keywords:
Ear Infection, AOM, Acute Otitis Media

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 an ear infection (acute otitis media). 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 look at whether certain factors such as how sick the child is at the start, presence of fever, age, or how well antibiotics work. The results will help guide better treatment decisions for children with ear infections.

Contact(s): Jane Luce, MPH - lucej2@upmc.edu
Phase: PHASE4
System ID: NCT07730814

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