



Dear Colleague,

I am writing to make you aware of an important clinical trial supported by the National Institutes of Health (NIH) that we are conducting at Children's Hospital of Pittsburgh of UPMC (Oakland) and at some of the affiliated PittNet practices. The study evaluates the efficacy of tympanostomy tubes for children with recurrent acute otitis media (rAOM) to determine whether children ages 6 to 35 months with rAOM benefit from having tympanostomy tubes or whether they can be effectively treated with antibiotics for each ear infection.

We invite you to actively participate in this research program by referring parents whose children are between the ages of 6 to 35 months and have risk factor(s) for rAOM. The efficacy of tympanostomy tubes, assumedly by maintaining middle-ear ventilation, remains unclear, and the benefits of tubes must be balanced against risks of anesthesia, complications and sequelae of surgery, and cost. In a phase 3 randomized, clinical trial, children at risk for rAOM, aged 6-35 months will be followed prospectively and examined promptly with new respiratory illnesses to accurately document episodes of AOM. Those who meet criteria for rAOM will be randomized to tympanostomy tubes or nonsurgical management and followed for 2 years. We will compare the average number of ear infections, changes in nasopharyngeal colonization and cost-effectiveness of each approach. Findings of this new study will provide clinicians and parents with dependable evidence concerning the overall effects of tympanostomy tubes compared with nonsurgical management in children with recurrent ear infections of varying degrees of severity, enabling evidence-based decisions regarding an important component of the children's healthcare.

We will keep you updated about the enrollment and progress of your patients participating in our study. Our purpose is not to assume the care of your patients, but only to carefully follow this group of children.

You can find information about this study on Children's Hospital's Web site at <http://www.chp.edu/research/clinical-studies/general-academic-pediatrics/recurrent-acute-otitis-media>.

As always, thank you for your support of our research program. If you have any questions, please do not hesitate to contact me at 412-999-EARS (3277) or hoberman@chp.edu.

Very truly yours,

Alejandro Hoberman, MD
Chief, Division of General Academic Pediatrics
Department of Pediatrics, Vice Chair for Clinical Research