

# Scott & White Hospital & Clinics

## Clinical Research at Scott & White

**Study Title:** C-05-36: Safety and Efficacy Evaluation of Topical Moxidex Otic Solution Compared to Moxifloxacin Solution in the Treatment of Acute Otitis Media with Otorrhea through Tympanostomy Tubes (AOMT)

**Project ID#:** 050286

**Department:** Pediatrics

**Sponsor:** Alcon

### Brief Synopsis of the Study

Condition(s):	Treatment(s):
Children 6 months to 12 years of age with ear drainage with tympanostomy tubes	Child will receive one of two investigational eardrops twice a day for 7 days of treatment.

The purpose of this research study is to compare the safety and effectiveness of moxifloxacin/dexamethasone (Moxidex) Otic (Ear) Solution, an investigational drug, to Moxifloxacin Otic Solution, an investigational drug, in treating ear infections in children. The difference in these drugs is that Moxidex does contain an anti-inflammatory, dexamethasone, and Moxifloxacin does not.

### Who is eligible to participate in the study?

**Age:** Between the ages of 6 months and 12 years of age.

**Gender:** Male and Female

Males and females between the ages of 6 months and 12 years old are eligible if they have had ear drainage for less than 21 days and also have tympanostomy tubes. Subjects must also meet other inclusion/exclusion criteria.

### What may be involved/required for subject participation? (Visits, tests and/or logs, etc.)

This study involves 4 visits over 15-18 days. The parent will be required to call in to a phone diary twice a day for the duration of the study. The child's ear will be cleaned at the first visit using a suction method to grow and identify the bacteria causing the infection. The child may require a second cleaning if no improvement is seen. No blood draws are required for this study. Participants will be reimbursed for time and travel.

**For More Information Contact:**

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