

ATOMIC Ears: A Phase IIB randomised controlled trial to assess safety, tolerability and acceptability of a 5-day Dornase alfa treatment as an adjunct therapy to ventilation tube insertion for otitis media in children

ACTRN12619001306101

Status	RECRUITING
Phase	Phase 2
Sponsor	Telethon Kids Institute
Enrollment	120 participants

Plain Language Summary

Ear infections are extremely common in young children, and many children suffer repeated infections that can affect their hearing and development. For children with chronic fluid behind the eardrum (glue ear) or recurrent infections, a common surgical treatment is the insertion of ventilation tubes — also called grommets — to help drain the fluid and allow air in. However, some children continue to experience infections even after this surgery.

This trial, called ATOMIC Ears, is testing whether a drug called Dornase alfa — which is normally used for cystic fibrosis but is being repurposed here — can improve outcomes after grommet surgery. The idea is that bacteria in middle ear infections protect themselves using a DNA-based structure called a biofilm, and Dornase alfa can break down this DNA scaffolding, making the bacteria easier to clear. Parents will administer the drug as ear drops at home for five days after surgery.

Your child may be eligible if they are aged 6 months to less than 5 years and are about to have ventilation tubes inserted due to chronic glue ear or recurrent ear infections. Children with cystic fibrosis, serious immune conditions, chromosomal disorders, or allergies to the study medication are not eligible. This study represents a hopeful new approach for children who are caught in a cycle of ear infections.

Key Eligibility Criteria

Inclusion (8)

- Aged 6 months to less than 5 years of age.
- Undergoing surgery for ventilation tube insertion for recurrent acute otitis media or chronic otitis media with effusion, either unilateral or bilateral, which will be performed by a collaborating ear, nose and throat (ENT) surgeon.
- N.B. participants undergoing concurrent adenoidectomy and/or tonsillectomy are permitted to participate.
- Has either a current medically confirmed unilateral or bilateral middle ear effusion that has been present for 3 months or longer and/or had 3 episodes of medically confirmed acute otitis media in the previous 6 months or 4 or more episodes in the previous 12 months.
- Considered to be generally healthy as established by medical history before entering the study, excluding medical conditions listed in inclusion criterion 3.

... and 3 more (see full listing online)

Exclusion (8)

- Has a diagnosed sensorineural hearing loss, cystic fibrosis, a craniofacial disorder or immotile cilia syndrome.
- Has a confirmed or suspected immunosuppressive or immunodeficient condition.
- Has a suspected or diagnosed genetic syndrome or chromosomal disorder.
- Has experienced an allergic reaction to protein of Chinese Hamster Ovary origin.

<https://www.anzctr.org.au/Trial-Registration/TrialRegistrationDetails.aspx?ACTRN12619001306101>

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... and 3 more (see full listing online)

Locations (5 total)

St John of God Hospital, Subiaco - Subiaco, WA, Australia

Subiaco Private Hospital - Subiaco, WA, Australia

South Perth Hospital - South Perth, WA, Australia

... and 2 more locations