A non-invasive treatment for Otitis Media with Effusion

ACTRN12621000949886

Status	RECRUITING
Sponsor	Curtin University
Enrollment	25 participants

Plain Language Summary

This study is testing a new non-surgical device to treat glue ear (otitis media with effusion, or OME) in young children. Glue ear is a very common childhood condition where fluid becomes trapped behind the eardrum, causing temporary hearing loss. In most cases it resolves on its own, but in persistent cases, children often require a surgical procedure called grommet insertion. The device being tested uses gentle air pressure through a specially designed drinking bottle to open the Eustachian tube — the canal that drains the middle ear — and allow the trapped fluid to drain naturally.

This is a usability and effectiveness study to see whether children can use the device comfortably and whether it successfully drains the fluid. Researchers will confirm fluid is present using a tympanogram test before enrollment and will monitor outcomes after treatment.

To be eligible, the child must be aged 2 to 12, have a confirmed Type C tympanogram (indicating fluid in the middle ear), be able to drink from a bottle without fear of the device, and have a parent who speaks English. Children with nasal congestion, swallowing problems, craniofacial abnormalities, or an active ear infection are not eligible. This study is run by Curtin University.

Key Eligibility Criteria

Inclusion (4)

- •Full understanding of the protocol and signed informed consent by the legal guardian
- •Able to drink from the bottle appropriately without fear of the device.
- •Parent English speaking
- •Type C tympanogram

Exclusion (7)

- •Nasal congestion
- •VPI (Velo-palatal incompetence/velopharyngeal insufficiency)
- •A history aspiration or known swallowing dysfunction
- •The presence of craniofacial abnormalities
- •Other contraindications for positive nasal pressurization

... and 2 more (see full listing online)

Locations (1 total)

California, United States of America

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