

# Antibiotics for Asymptomatic Acute Otitis Media

ACTRN12608000424303

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 3, Phase 4
<b>Sponsor</b>	Menzies School of Health Research
<b>Enrollment</b>	300 participants

## Plain Language Summary

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This study is testing whether a short course of antibiotics (azithromycin) helps Aboriginal children who have a middle ear infection with no pain or fever — called asymptomatic acute otitis media. Sometimes the eardrum bulges out from fluid buildup even when the child does not seem sick. Researchers want to find out if treating this early with antibiotics helps clear up the problem faster than simply waiting and watching.

You may be eligible if:

- Your child is an Aboriginal child living in a participating community
- Your child is between 6 and 30 months old
- Your child has been diagnosed with a bulging eardrum but has no ear pain or fever
- You are able to bring your child back to the clinic for follow-up visits at 7, 14, and 28 days
- You have given signed informed consent

You may NOT be eligible if:

- Your child has ear pain or fever along with the ear infection
- Your child has had recent ear discharge or perforation (within the last 7 days)
- Your child has chronic ear disease with ongoing discharge
- Your child was already enrolled in this study before
- Your child received antibiotics in the last 7 days (not including ear drops)
- Your child has a more serious illness that already needs antibiotics
- Your child is allergic to azithromycin
- Your child has an immune system problem

Talk to your doctor about whether this trial might be right for you.

## Key Eligibility Criteria

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### Inclusion (5)

- Informed consent obtained and signed
- All Aboriginal children aged 6 months and 30 months of age on the date of randomisation who are resident in participating communities will be eligible to be screened for asymptomatic acute otitis media without perforation.
- a.) A bulging tympanic membrane.
- b.) No associated symptoms at the time of diagnosis (including ear pain or fever).
- Children who have a diagnosis of asymptomatic acute otitis media who are able to attend the clinic for follow up visits at day 7, day 14 and day 28.

### Exclusion (8)

- Acute otitis media with ear pain or fever
- Acute otitis media with recent onset of perforation and discharge (within 7 days)
- Chronic suppurative otitis media

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12608000424303>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [anzctr.org.au](http://anzctr.org.au). Generated by [ClinicalTrialsFinder.org](http://ClinicalTrialsFinder.org).

- Have received antibiotics in the previous 7 days (not including topical antibiotics)  
... and 3 more (see full listing online)

## Locations (1 total)

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Australia