

Effect of Chitodex gel in ear drum repair (tympanoplasty) surgery

ACTRN12621001058864

Status	RECRUITING
Sponsor	Central Adelaide Local Health Network (CALHN)
Enrollment	84 participants

Plain Language Summary

This study is comparing two different materials used to pack the middle ear after surgery to repair a perforated eardrum (tympanoplasty). A perforated eardrum can cause hearing loss and repeated ear infections, and surgery is performed to close the hole using a tissue graft. To support the graft while it heals, surgeons pack the middle ear cavity with a filler material — traditionally a product called Gelfoam.

The study is testing whether a newer gel called Chitodex — made from chitin, a natural material found in shellfish — performs better than Gelfoam. Chitodex has anti-inflammatory and wound-healing properties that may reduce scarring and improve surgical success rates. Participants will have their outcomes tracked at two weeks, six weeks, three months, and six months after surgery, including an MRI scan at four weeks.

You may be eligible if you are 18 or older, have a confirmed eardrum perforation with at least 15dB of hearing loss in the affected ear, and are already scheduled for tympanoplasty or related middle ear surgery. You are not eligible if you have an allergy to shellfish or the antibiotic ciprofloxacin, are pregnant or breastfeeding, or have certain blood disorders.

Key Eligibility Criteria

Inclusion (9)

- Individuals who have otoscopic evidence of tympanic membrane perforation that is also confirmed by tympanometry (Defined as a Type B tympanogram, with elevated EAC volume) AND
 - The TM perforation is associated with at least 15dB of conductive hearing loss on the affected side AND
 - Are indicated to undergo closure of the perforation via tympanoplasty surgery
 - OR Individuals who are indicated for ossiculoplasty due to ossicular chain disruption and its sequelae
 - OR Individuals who are indicated for mastoidectomy for COM or its sequelae eg cholesteatoma
- ... and 4 more (see full listing online)

Exclusion (7)

- Operative ear is the better or only hearing ear
 - dysfunction during otoscopic and tympanometric examination
 - Known allergy to shellfish or ciprofloxacin antibiotics
 - Pregnant or breastfeeding
 - Hepatitis, HIV or any blood disorders
- ... and 2 more (see full listing online)

Locations (6 total)

The Queen Elizabeth Hospital - Woodville, SA, Australia
Lyll McEwin Hospital - Elizabeth Vale, SA, Australia
Calvary Wakefield Hospital - Adelaide, SA, Australia
... and 3 more locations

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12621001058864>

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