

Tissue-engineered Regeneration of Tympanic Membrane (Ear Drum) Perforations

ACTRN12613001338752

Status RECRUITING
Sponsor Otolaryngology, Head & Neck Surgery, UWA
Enrollment 60 participants

Plain Language Summary

This study is testing a treatment for chronic (long-lasting) holes in the eardrum (tympanic membrane perforations). The treatment uses a growth factor called bFGF (basic fibroblast growth factor) to try to help the eardrum heal itself. A scaffold material is also used to support the healing tissue.

You may be eligible if:

- You are aged between 5 and 95 years
- You have a dry eardrum perforation (hole in the eardrum with no active infection)
- The hole is 50% or less of the total eardrum surface

You may NOT be eligible if:

- You have an active middle ear infection
- You have had ear discharge in the last 3 months
- You have an allergy to bFGF or the scaffold material
- You have problems with the tiny bones in the middle ear (ossicular chain pathology)

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

Key Eligibility Criteria

Inclusion (1)

- dry ear drum perforation; perforation size smaller or equal to 50% percent of the drum surface

Exclusion (4)

- active middle ear infection
- ear discharge in the last 3 months
- allergy to bFGF or scaffold
- associated ossicular chain pathology

Locations (2 total)

Fremantle Hospital and Health Service - Fremantle, WA, Australia
Princess Margaret Hospital - Subiaco, WA, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12613001338752>

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