A single-arm feasibility trial evaluating a protein-based scaffold system with tissue transfer for the reconstruction of skull fractures

ACTRN12620001171909

Status	RECRUITING
Sponsor	Princess Alexandra Hospital
Enrollment	10 participants

Plain Language Summary

This feasibility study tests a new surgical technique for reconstructing skull defects — gaps in the skull bone caused by trauma, cancer, or infection. Currently, skull reconstruction often requires the use of synthetic plates (like titanium or PEEK plastic), which can sometimes fail, become infected, or not integrate well with the body. This study uses a natural protein scaffold combined with a patient's own living tissue transferred from another part of the body (free tissue transfer) to encourage the bone to regrow.

The hope is that the scaffold, seeded with the body's own cells, will gradually be replaced by real bone, resulting in a more natural and durable repair with fewer complications. Participants undergo the procedure at the Princess Alexandra Hospital in Queensland and are followed up for two years with CT scans and questionnaires to assess bone regeneration, cosmesis, and overall wellbeing.

You may be eligible if you are aged 18 to 55 (older patients may be considered on a case-by-case basis), have an acquired skull defect, have an expected survival of more than 36 months, and are willing and able to comply with study requirements. People with active skull infection, immunodeficiency (including HIV), are on chemotherapy or corticosteroids, or have significant concurrent illness are not eligible.

Key Eligibility Criteria

Inclusion (5)

- •Acquired intercalary defect of the calvarium
- •Patient aged >18 and <55 years
- •Patients aged over 55 may still be eligible for trial after assessment by and at the discretion of the investigators with documentation to that effect provided for the trial documents pertaining to such patients.
- •Patient willing and able to comply with the study requirements.
- •Patient capable of providing valid informed consent.

Exclusion (6)

- •Active infection of the calvarium at the time of study inclusion, manifest as a failed trial off antibiotics in chronic infected cases.
- •Patient unwilling or unable to provide fully informed consent including but not limited to patients with intellectual or mental impairment.
- •Patient with a known history of immunodeficiency including HIV, concomitant systemic corticosteroid therapy, chemotherapy, synchronous haematological malignancy or other cause for secondary/primary immunodeficiency.
- •Known severe concurrent or inter-current illness including: cardiovascular, respiratory or immunological illness, psychiatric disorders, or alcohol or chemical dependence that would, in the opinion of the primary investigator, compromise their safety or compliance or interfere with interpretation of study results.
- •Patient life expectancy < 36 months.

... and 1 more (see full listing online)

Locations (1 total)

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12620001171909

ACT,NSW,NT,QLD,SA,TAS,WA,VIC, Australia