

Silent and Apparent Neurological Injury in Transcatheter Aortic Valve Implantation (TAVI)

ACTRN12613000083796

Status	RECRUITING
Sponsor	Critical Care Research Group (CCRG)
Enrollment	80 participants

Plain Language Summary

This study is investigating the risk of stroke and changes in brain function in patients who receive a transcatheter aortic valve implantation (TAVI) — a minimally invasive procedure to replace a damaged heart valve without open surgery. TAVI is used for high-risk patients who cannot safely have traditional surgery. Researchers are using brain MRI and cognitive tests to better understand how often silent (symptomless) brain injury occurs during the procedure and what causes it.

You may be eligible if:

- You are scheduled to have a TAVI procedure using the Edwards SAPIEN-XT valve via a standard route (through the femoral artery, aorta, or heart apex)
- You are able to give your own informed consent

You may NOT be eligible if:

- You have significant pre-existing neurological impairment (modified Rankin Score of 3 or more)
- You cannot have an MRI (e.g., you have a pacemaker, metal implant, or severe claustrophobia)
- You do not speak English well enough to complete cognitive tests
- You have had a previous aortic valve repair or replacement
- You also need coronary artery bypass surgery at the same time

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

Key Eligibility Criteria

Inclusion (1)

- All consenting patients undergoing transcatheter aortic valve implantation (TAVI) via the transfemoral, transaortic and transapical routes with the Edwards SAPIEN-XT valve under general anaesthetic.

Exclusion (6)

- Lacks capacity to consent for him or herself.
- Pre-existing neurological impairment measured as modified Rankin Score ≥ 3 .
- Contraindication to MRI (including incompatible metallic prosthesis/foreign body, inability to lie flat, claustrophobia requiring sedation)
- Non or poor English-speaking due to nature of cognitive testing and unknown validity in such populations
- Previous aortic valve repair/replacement.

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

Locations (2 total)

The Prince Charles Hospital - Chermside, NSW,QLD, Australia

Royal Prince Alfred Hospital - Camperdown, NSW,QLD, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12613000083796>

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