Continuous mONitoring of recovery iN acutE isChaemic sTroke (CONNECT) - Phase 1

ACTRN12622001485729

Status	RECRUITING
Sponsor	The George Institute
Enrollment	50 participants

Plain Language Summary

When a major stroke occurs due to a blocked artery in the brain, every minute counts. Detecting when a patient's condition is deteriorating rapidly is critical — but current monitoring relies on nurses checking vital signs and neurological status at regular intervals, which means warning signs can be missed between checks. The CONNECT study is testing a new wearable device called the NurofluxTM, which is placed on the head and continuously monitors brain blood flow and neurological function, with the aim of detecting deterioration the moment it happens.

In Phase 1 of this study, 50 patients with confirmed large-vessel occlusion strokes will wear the device after their treatment to help researchers determine the right detection thresholds — essentially calibrating the device so it can reliably identify when something is going wrong. Safety, comfort, and practical usability in a hospital setting will also be assessed.

You may be eligible if you are 18 or older, have had an acute ischaemic stroke caused by a large-vessel blockage in the front of the brain confirmed within 24 hours, have a moderate-to-severe stroke severity score (NIHSS above 4), and are able to consent directly or through a representative. You would not be eligible if you have had brain surgery in the past month, have had a seizure since your stroke, have skin conditions that prevent electrode placement, or have severe dementia or extreme agitation.

Key Eligibility Criteria

Inclusion (4)

- Adults (age >= 18 years);
- AIS (initial diagnostic scan within 24 hours from symptom onset or last known well time) in anterior circulation due to large vessel occlusion (LVO, occlusion at the internal carotid artery, the middle cerebral artery horizontal or insular segment, or proximal site of the anterior cerebral artery), diagnosed by clinician and confirmed on CT with/without angiography;
- At least moderate neurological severity (National Institute of Health Stroke Scale [NIHSS] score >4); and
- Provision of consent.

Exclusion (6)

- Recent (<1 months) brain surgery;
- Evidence of seizure activity from stroke symptom onset to study inclusion;
- Having history of severe skin rash due to ECG/EEG electrode patches;
- Skin conditions on scalp or face that preclude safe use of the device (local infections, rashes, fragile skin, etc.);
- Having difficulties to wear the device stably (e.g., patients with severe dementia, extreme agitation, or susceptible to stress).

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

Locations (2 total)

Royal Prince Alfred Hospital - Camperdown, NSW, Australia
Prince of Wales Hospital - Randwick, NSW, Australia

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622001485729

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