

Stroke in patients with Very large Ischaemic Core: Assessment of Reperfusion therapy Impact on Outcome (SICARIO-VLC)

ACTRN12622000880741

Status	RECRUITING
Sponsor	The University of Newcastle
Enrollment	150 participants

Plain Language Summary

SICARIO-VLC is a clinical trial for people who have had a large ischaemic stroke — where a blood clot blocks an artery and causes a significant area of brain tissue to be at risk. When the affected area of the brain is very large (over 100 mL), doctors have traditionally been reluctant to attempt clot removal (thrombectomy), fearing the risks might outweigh the benefits. This trial challenges that assumption.

Participants are randomly assigned to receive either standard medical care or endovascular thrombectomy — a procedure where a catheter is guided through a blood vessel to physically remove the clot from the brain. The primary question is whether thrombectomy prevents the worst outcomes (such as death or severe disability) in patients with very large stroke cores.

You may be eligible if you are 18 or older, have had a large vessel occlusion stroke within the last 24 hours, have a very large ischaemic core on imaging (over 100 mL), and were previously functioning well (minimal disability). People with brain bleeding, severe pre-existing disability, vertebral or basilar artery occlusions, or a terminal illness are not eligible. Time is critical — the procedure must be started within two hours of brain imaging.

Key Eligibility Criteria

Inclusion (7)

- Patients presenting with acute hemispheric ischemic stroke with onset (or the time last known to be well) within 24 hours.
- Presence of a baseline ischemic core of >100 mL (SICARIO-VLC) on CT perfusion imaging or diffusion-perfusion MRI processed with automated perfusion volumetric analysis (MISar - Apollo Medical Imaging-, being the preferred software for the trial due to less variability in its outputs).
- Patient's age is 18 years or above
- Premorbid modified Rankin Scale score 0 to 2.
- Presence of a large vessel occlusion on CTA or MRA.

... and 2 more (see full listing online)

Exclusion (6)

- Intracranial haemorrhage (ICH) or other diagnosis (e.g. tumour) identified by baseline imaging.
- Vertebro-basilar artery occlusion
- Pre-stroke mRS > 2 (indicating significant previous disability)
- Any terminal illness such that patient would not be expected to survive more than 1 year.
- Any condition that, in the judgment of the investigator could impose hazards to the patient if study therapy is initiated or affect the participation of the patient in the study.

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

Locations (14 total)

John Hunter Hospital - New Lambton, NSW,SA,VIC, Australia

Liverpool Hospital - Liverpool, NSW,SA,VIC, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622000880741>

Prince of Wales Hospital - Randwick, NSW,SA,VIC, Australia

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... and 11 more locations

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622000880741>

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