

# Early Administration of PCSK9 Inhibitors After Thrombectomy for Atherosclerotic Acute Ischemic Stroke: A Randomized Controlled Trial

NCT07295366

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 4
<b>Sponsor</b>	The Affiliated Hospital of Xuzhou Medical University
<b>Enrollment</b>	60 participants

## Key Eligibility Criteria

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### Inclusion (10)

- Age 18-85 years old, gender not limited, gender ratio not limited.
- The clinical diagnosis was acute ischemic stroke with occlusion of the anterior circulation large vessels. CTA/DSA confirmed that the responsible vessel for this stroke occlusion was located in the intracranial segment of the internal carotid artery and the M1 segment of the middle cerebral artery.
- The time from onset to puncture is within 24 hours, and the patient receives mechanical thrombectomy (MT) (including direct thrombectomy and intravenous thrombolysis bridging thrombectomy), with postoperative vascular recanalization reaching mTICI grade 2b or 3. The surgical indications and time window follow the current guidelines and imaging criteria of key randomized controlled trials (RCTs). The definitions are as follows: Early window (0-6 h): Meeting the usual EVT indications (anterior circulation LVO, baseline NIHSS  $\leq 6$ , ASPECTS  $\geq 6$ , or center-defined criteria), the interventional team decides to perform MT; Late window (6-24 h): Meeting one of the imaging selection criteria of DAWN or DEFUSE-3 (based on CTP-RAPID or MRI-DWI/perfusion):
  - DAWN (6-24 h) (any one): Age  $\leq 80$  years: NIHSS  $\leq 10$  and core infarct volume  $< 21$  mL; Age  $< 80$  years: NIHSS  $\leq 10$  and core  $< 31$  mL; Age  $< 80$  years: NIHSS  $\leq 20$  and core 31-51 mL.
  - DEFUSE-3 (6-16 h) (all conditions must be met): Core  $< 70$  mL, mismatch ratio (penumbra/core)  $\leq 1.8$ , mismatch volume  $\leq 15$  mL, and Tmax  $> 6$  s volume  $> 15$  mL.
- ... and 5 more (see full listing online)

### Exclusion (10)

- Non-atherosclerotic lesions (such as arterial dissection, Moyamoya disease, vasculitis, embolism of unknown origin, etc.).
- Patients who present with significant intracranial hemorrhage or excessively large cerebral infarction volume upon admission, making them unsuitable for continued participation in the study.
- The cause of stroke is cardioembolism (such as a history of heart disease such as atrial fibrillation or valvular heart disease).
- Individuals with a clear history of allergy to evolocumab or its excipients.
- Patients with severe liver and kidney dysfunction: baseline alanine aminotransferase (ALT) or aspartate aminotransferase (AST)  $> 3$  times the upper limit of normal, or significantly reduced creatinine clearance (eGFR  $< 30$  mL/min/1.73m<sup>2</sup>).
- ... and 5 more (see full listing online)

## Locations (1 total)

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Affiliated Hospital of Xuzhou Medical University, Xuzhou, Jiangsu, China

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<https://clinicaltrials.gov/study/NCT07295366>

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