

Design & organization

- Phase 3 PROBE trial with deferred consent
- Transdermal nitroglycerin 5 mg/day for 24h plus standard care vs. standard care
- Randomisation (1:1) and treatment started by paramedics in the ambulance
- Target sample: n=1400
- 6 ambulance services
- 17 hospitals



Eligibility

- Adult patients with probable acute stroke
 - FAST score 2 or 3
 - SBP \geq 140 mmHg
 - Symptoms started <3 hours ago
- Key exclusion criteria:
 - Pre-stroke dependency
 - Glasgow Coma Scale <8
 - Hypersensitivity to nitroglycerin

Results

- Stopped early for futility on June 24th 2021
- 326 patients included
 - 171 nitroglycerin
 - 155 control
- Primary outcome neutral →
- Interaction for stroke type on primary outcome ↓

acOR: 0.94, 95%CI: 0.63-1.41

