MR CLEAN-NO IV: Intravenous treatment followed by intra-arterial treatment versus direct intra-arterial treatment for acute ischemic stroke caused by a proximal intracranial occlusion.

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RATIONALE

- Rates of early recanalization with intravenous rtPA (IVT) in patients with acute ischemic stroke (AIS) with proximal intracranial occlusion are low
- Rates of symptomatic intracranial hemorrhage (sICH) in the MR CLEAN trial were equal in both treatment groups (IVT vs IVT+intra-arterial treatment [IAT]) → complication of IVT
- Direct IAT was at least as effective as IVT+IAT in patients who had a contraindication for IVT

OBJECTIVES

- Determine effect of direct IAT compared with IVT+IAT on functional outcome
- Non-inferiority of direct IAT relative to IVT+IAT on functional outcome

STUDY DESIGN

Prospective, randomized clinical trial with observer-blinded assessment of primary outcome (PROBE).

Patient flow in the study

PRIMARY OUTCOME

Common Odds Ratio of **modified Rankin Scale score at 3 months (mRS)**

SECONDARY / SAFETY OUTCOMES

- Mortality at 90 days ($\pm$ 14 days)
- sICH
- Extended treatment in cerebral ischemia (eTICI) score on final angiography of IAT
- Recanalization rate at 24 hours, assessed with CTA/MRA
- Score on the NIHSS at 24 hours and 5-7 days, or at discharge
- Final infarct volume at 5-7 days

STUDY POPULATION

Sample size: 540 patients.

Inclusion criteria

- AIS
- Proximal intracranial occlusion (CTA/MRA)
- NIHSS $\geq$ 2
- Written deferred consent

Exclusion criteria

- Prestroke mRS >2
- Any contraindication for IVT (AHA guideline)

KEY STATISTICS

- Netherlands: 2 participating centers, 15 planned to join
- Belgium: UZ Leuven planned to join
- France: Montpellier CHU planned to join

TRIAL PROGRESS

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