SETPOINT2

*Stroke-related Early Tracheostomy vs Prolonged Orotracheal Intubation in Neurocritical care Trial 2*

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Background - Tracheostomy after Stroke

- Dysphagia in patients with severe stroke 50-80%
- Extubation failure in ventilated patients with stroke 30-40%
- Tracheostomy in ventilated patients with stroke 30%
- Proposed benefits of Early Tracheostomy: Less laryngeal lesions, work of breathing, sedation, duration of ventilation,...
- Unclear: How to set the best point in time for Tracheostomy?

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SETPOINT2 - Protocol

**Design:** Multicenter, PROBE

**Centers:** 25, GER + USA

**Population:** AIS, ICH, SAH

**Intervention:** PDT before day 5

**Control:** PDT on/after day 10 or previous extubation

**Primary Endpoint:** mRS (0-4 vs 5+6) after 6 Mon.

**Sample:** 380 (for ES 15%)
SETPOINT2- Primary outcome (6 month-mRS)

- No difference in mRS 0-4 at 6 mo
- 43.5% vs 47.1%
- No differences in all sensitivity analyses
- No differences in secondary outcomes on survival, ICU course, safety
Main Conclusion

Among ventilated ICU patients with severe ischemic and hemorrhagic stroke, a strategy of early tracheostomy, compared with a standard approach to tracheostomy, did not significantly improve functional outcome at 6 months.