ARTEMIS TRIAL

A Reduction in Time with Electronic Monitoring In Stroke trial

Gaia T. Koster¹, Adrien E. Groot², T. Truc My Nguyen¹, Jonathan M. Coutinho², Jan Bosch³, Heleen M. den Hertog⁴, Ale Algra^{5,6}, Marieke Wermer¹, Yvo B. Roos², Nyika Kruij¹, for the ARTEMIS investigator group.

¹From the Department of Neurology, Leiden University Medical Center Leiden. ²From the Department of Neurology, Academic Medical Center Amsterdam. ³RAV Hollands Midden, Leiden. ⁴Department of Neurology, Medical Spectrum Twente, Enschede. ⁵Department of Clinical Epidemiology, Leiden University Medical Center, Leiden. ⁶Julius Centre, University Medical Center, Utrecht.

BACKGROUND

For the clinical benefit of intravenous thrombolysis (IVT) and intra-arterial thrombectomy (IAT), **time is the most crucial factor**.

The delay from alarming the Emergency Medical Services (EMS) dispatch office until initiation of reperfusion therapy depends on logistics and collaboration between various caregivers in this trajectory (i.e. **total system delay [TSD]**, see Figure 1).

Figure 1. Schematic overview of the acute care trajectory for patients with a suspected stroke

METHODS

Design: Multicenter, multicenter, randomized open end-point trial.

Inclusion criteria: all consecutive patients over 18 years with suspected stroke and eligibility for IVT and/or IAT, identified by the EMS dispatch office or by paramedic on-site.

Run-in phase: implementation of hardware and time registration will first be tested during the run-in phase.

Randomization phase: real-time audio-visual feedback on actual TSD will be provided to caregivers. Randomization will be per patient.

Sample size: by including 75 IAT and 225 IVT patients in each arm, we will be able to demonstrate a 20-minute reduction on TSD to IAT and a 10-minute reduction on TSD to IVT ($\alpha = 0.05$ and power = 0.8).

AUTOMATIC TRACKING SYSTEM

Patients will receive a **wristband with an iBeacon** which emits a Bluetooth signal. **Handhelds and tablets** along the route will pick-up this signal and register the time. The following times will be recorded:

- First contact EMS
- Arrival of ambulance at patient
- Departure of ambulance to hospital
- Door hospital
- Shock room/CT-room hospital
- Needle (IVT)
- Arrival at angio suite
- Groin puncture (IAT)
- Moment of reperfusion or last angio run (IAT).

INTERVENTION

Real-time audio-visual feedback to caregivers on actual TSD

OUTCOME MEASURES

Primary outcome: Total System Delay to IVT and IAT.

Secondary outcomes: percentage of patients treated with IVT and/or IAT, functional outcome after 90 days (measured with modified Rankin Scale score), complications (e.g. symptomatic intracranial hemorrhage) and cost-effectiveness.

RESULTS

Total number of current inclusions: 13 patients (12 IVT and 5 IAT)

Leiden and Amsterdam are currently recruiting patients.

Twente will start in June 2018.

ARTEMIS investigator group: A. Algra, J. Bosch, J.M. Coutinho, A.E. Groot, H.M. den Hertog, G.T. Koster, N.D. Kruij, V.I.H. Kwa, T.T.M. Nguyen, Y.B.W.E.M. Roos, S.M. van Schaik, E.L.L.M. de Schryver, M.C. Visser, M.A.A. van Walderveen, M.J.H. Wermer.

www.artemistrial.org artemis@amc.uva.nl