Statistical analysis plan of the head position in acute ischemic stroke trial pilot (HEADPOST pilot)

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© 2016, © 2016 World Stroke Organization. Background: The HEADPOST Pilot is a proof-of-concept, open, prospective, multicenter, international, cluster randomized, phase IIb controlled trial, with masked outcome assessment. The trial will test if lying flat head position initiated in patients within 12 h of onset of acute ischemic stroke involving the anterior circulation increases cerebral blood flow in the middle cerebral arteries, as measured by transcranial Doppler. The study will also assess the safety and feasibility of patients lying flat for ?24 h. The trial was conducted in centers in three countries, with ability to perform early transcranial Doppler. A feature of this trial was that patients were randomized to a certain position according to the month of admission to hospital. Objective: To outline in detail the predetermined statistical analysis plan for HEADPOST Pilot study. Methods: All data collected by participating researchers will be reviewed and formally assessed. Inf