

# Statistical analysis plan for the Head Position in Stroke Trial (HeadPoST): An international cluster cross-over randomized trial

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## Resumen

**Background:** There is evidence to indicate that the lying flat head position increases cerebral blood flow and oxygenation in patients with acute ischemic stroke, but how these physiological effects translate into clinical outcomes is uncertain. The Head Position in Stroke Trial aims to determine the comparative effectiveness of lying flat (0 degrees) compared to sitting up ( $\geq 30$  degrees) head positioning, initiated within 24 h of hospital admission for patients with acute stroke.

**Design:** An international, pragmatic, cluster-randomized, crossover, open, blinded outcome assessed clinical trial. Each hospital with an established acute stroke unit (cluster) site was required to recruit up to 140 consecutive cases of acute stroke (one phase of head positioning before immediately crossing over to the other phase of head positioning), including both acute ischemic stroke and intracerebral hemorrhage, in each randomized head position as a 'business as usual' policy.

**Objective:** To outline in detail the predetermined statistical analysis plan for the study.

**Methods:** All accumulated data will be reviewed and formally assessed. Information regarding baseline characteristics of patients, their process of care and management will be outlined, and for each item, statistically relevant descriptive elements will be described. For the trial outcomes, the most appropriate statistical comparisons are described.

Results: A statistical analysis plan was developed that is transparent, verifiable, and predetermined before completion of data collection.

Conclusions: We developed a predetermined statistical analysis plan for Head Position in Stroke Trial to avoid analysis bias arising from prior knowledge of the findings, in order to reliably quantify the benefits and harms of lying flat versus sitting up early after the onset of acute stroke.

## Palabras clave

**Palabras clave de autor:**[Stroke](#); [ischemic stroke](#); [clinical trial](#); [head position](#); [treatment](#); [nursing care](#)

**KeyWords Plus:**[ACUTE ISCHEMIC-STROKE](#); [BLOOD-FLOW-VELOCITY](#); [CEREBRAL OXYGENATION](#); [ASSOCIATION](#); [GUIDELINES](#); [MANAGEMENT](#); [PROTOCOL](#); [CARE](#)

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